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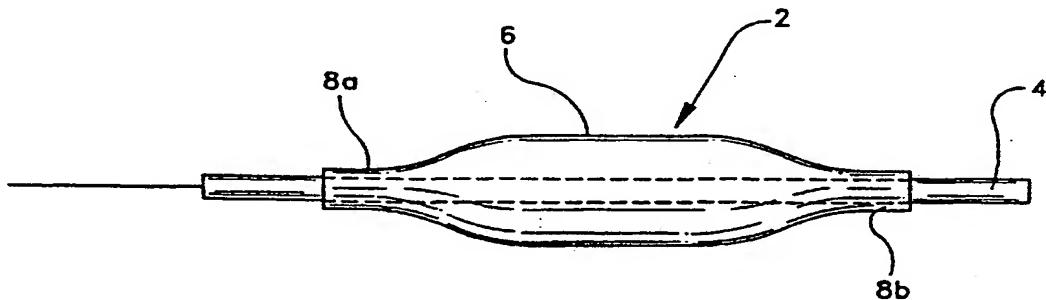
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(54) Title: DILATATION BALLOONS CONTAINING POLYESTERETHERAMIDE COPOLYMER



(57) Abstract

Disclosed is a dilatation balloon having a single layer containing polyesteretheramide copolymer. The dilatation balloon may also contain polyamide and/or additional polymers, and may contain substantially no polyetheramide having substantially no ester linkages.

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DILATATION BALLOONS CONTAINING
POLYESTERETHERAMIDE COPOLYMER
Background of the Invention

The present invention is generally directed to
5 dilatation balloons containing polyesteretheramide
copolymer.

The use of balloon catheters for coronary
angioplasty is known in the art. In an angioplasty
procedure, a partially occluded blood vessel, i.e., one
10 containing a stenosis, is treated by the use of an
expanding balloon member which presses the stenosis back
against the vessel wall. Typically, the expander member
or balloon is carried on the distal end of a dilatation
catheter which is routed through the vascular system to a
15 location within, for example, a coronary artery
containing a stenotic lesion. Following placement of the
expander member across the lesion as desired, fluid is
introduced into the proximal end of the catheter to
inflate the expander member to a relatively high
20 pressure, thereby restoring patency to the vessel.

Coronary angioplasty procedures and angioplasty devices
are described in detail in Vliestra et al., "Coronary
Balloon Angioplasty," Blackwell Scientific Publications
(1994).

25 Medical balloons that are known in the art are
disclosed in the following documents: U.S. Patent Nos.
4 964 853 and 4 994 032 to Sugiyama et al; U.S. Patents
No. 4 906 244, 5 108 415, 5 156 612, 5 236 659, and
5 304 197, to Pinchuk et al; U.S. Patent Nos. 5 226 880
30 and 5 334 148 to Martin; U.S. Patent No. 5 250 069 to

Nobuyoshi et al; U.S. Patent No. 5,328,468 to Kaneko et al.; European Patent Application No. 0 566 755; and Japanese laid-open patent application No. 58-188463. (All documents cited herein, including the foregoing, are 5 incorporated herein in their entireties for all purposes.)

It is an object of the present invention to provide a balloon for an angioplasty device which is made, at least in part, of polyesteretheramide copolymer.

10 Other objects and advantages of the invention will become apparent to those skilled in the art through familiarization with the specification and claims herein.

Summary of the Invention

In sum, the present invention relates to a balloon 15 for an angioplasty device having a single polymeric layer. The layer may have from about 20 to about 100 weight percent polyesteretheramide copolymer and from about 0 to about 80 weight percent polyamide. The layer contains substantially no polyetheramide having 20 substantially no ester linkages. The polyesteretheramide copolymer may be a block or random copolymer. The polyesteretheramide copolymer may have a hardness of from about 45 Shore D to about 78 Shore D, preferably from about 55 Shore D to about 75 Shore D, and more preferably 25 from about 63 to about 72 Shore D. Even more preferably, the polyesteretheramide copolymer may have a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D. The single polymeric layer may contain at least about 2 weight percent polyamide such as nylon 30 12, nylon 11, nylon 6, nylon 6/6, nylon 4/6, and

combinations thereof. The single polymeric layer may further contain at least about 2 weight percent polymer such as polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof. The polymeric 5 layer may have at least about 40 weight percent polyesteretheramide copolymer and more preferably at least about 80 weight percent polyesteretheramide copolymer. The balloon may have from about 20 to about 80 weight percent nylon 12 and about 20 to about 80 weight 10 percent polyesteretheramide copolymer, preferably about 60 weight percent nylon 12 and about 40 weight percent polyesteretheramide copolymer. Alternatively, the balloon may have about 25 to about 80 weight percent nylon 4/6 and about 20 to about 75 weight percent 15 polyesteretheramide copolymer, preferably about 65 weight percent nylon 4/6 and about 35 weight percent polyesteretheramide copolymer.

The present invention also relates to a balloon for an angioplasty device having a single polymeric layer 20 consisting essentially of a polyesteretheramide copolymer. The polyesteretheramide copolymer may be a block or random copolymer. The polyesteretheramide copolymer may have a hardness of from about 45 Shore D to about 78 Shore D, preferably from about 55 Shore D to 25 about 75 Shore D, and more preferably about 63 to about 72 Shore D. Even more preferably the polyesteretheramide copolymer may have a hardness selected from 63 Shore D, 70 Shore D, and 72 Shore D. The balloon may consist of polyesteretheramide.

The present invention also relates to a balloon for an angioplasty device having a single polymeric layer having (a) at least 91 weight percent polyesteretheramide copolymer, (b) from 0 to 9 weight percent polyamide, and 5 (c) from 0 to 9 weight percent of a polymer other than polyesteretheramide and polyamide. The balloon may have at least about 95 weight percent polyesteretheramide copolymer.

Description of the Drawings

10 FIG. 1 is a perspective view of an expander member of the present invention joined to the distal end of a catheter;

FIG. 2 is a cross-sectional view of a balloon form used to make expander members of the present invention;

15 FIG. 3 is a schematic view of a mold apparatus used to make expander members of the present invention;

FIG. 4 shows a response surface that details the effects of processing variables and material selection on balloon wall thickness for PEBAX 6333 balloons;

20 FIG. 5 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 6333 balloons;

FIG. 6 shows a response surface that details the effects of processing variables and material selection on 25 balloon K-stat for PEBAX 6333 balloons;

FIG. 7 shows a response surface that details the effects of processing variables and material selection on balloon hoop stress for PEBAX 6333 balloons;

FIG. 8 shows a response surface that details the effects of processing variables and material selection on balloon wall thickness for PEBAX 7033 balloons;

5 FIG. 9 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 7033 balloons;

FIG. 10 shows a response surface that details the effects of processing variables and material selection on balloon K-stat 7033 for PEBAX 7033 balloons;

10 FIG. 11 shows a response surface that details the effects of processing variables and material selection on balloon hoop stress for PEBAX 7033 balloons;

FIG. 12 shows a response surface that details the effects of processing variables and material selection on 15 balloon wall thickness for PEBAX 7233 balloons;

FIG. 13 shows a response surface that details the effects of processing variables and material selection on balloon burst pressure for PEBAX 7233 balloons;

20 FIG. 14 shows a response surface that details the effects of processing variables and material selection on balloon K-stat for PEBAX 7233 balloons; and

FIG. 15 shows a response surface that details the effects of processing variables and material selection on 25 balloon hoop stress for PEBAX 7233 balloons.

Description of the Preferred Embodiments

With reference to FIG. 1, expander member 2 is attached to the distal end of a catheter shaft 4. The expander member 2, otherwise known as a balloon, has a single polymeric layer 6 which surrounds the catheter 30 shaft 4. The expander member 2 shown is bonded at two

bonding sites 8a,b by thermal bonding, by laser bonding, with adhesives, or by other methods known in the art.

The expander members of the present invention contain polyesteretheramide copolymer. The structure of 5 these polymers consists of regular and linear chains of rigid polyamide blocks and flexible polyether blocks. Such copolymers may be described by the following formula:



where PA is a polyamide block; and
where PE is a polyether block.

Polyesteretheramide copolymer materials are sold 15 under the trademark PEBAX by Atochem Inc. of Glen Rock, New Jersey. Properties of several grades of PEBAX are disclosed in Atochem's brochure entitled "PEBAX Polyether Block Amide" (December 1987).

The expander member of the present invention may 20 contain polyamide. Polyamide materials include nylon 12, nylon 11, nylon 6, nylon 6/6, and nylon 4/6. Such materials are sold under the trademark ZYTEL[®] by Dupont.

The expander member of the present invention may further contain a polymer other than polyesteretheramide 25 copolymer or polyamide, such as polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof.

The single polymeric layer making up the expander member may be a blend of suitable materials. Such a 30 blend may be created by mixing the desired resins and

then extruding these resins to form a parison. The single layer can also be a graft copolymer. Such a graft copolymer can be formed, for example, by reacting polyamide (such as Nylon 12) with polyphenylether graft 5 maleic anhydride (PPE-graft-MA). So called polymer alloys, and the like, are also included within the purview of this application.

The expander member of the present invention may be formed by first generating a parison in an extruder. The 10 parison will typically have an inside diameter of from about .01 to .031 inches (0.025 to 0.079 cm), and a wall thickness of from about .0035 to .015 inches (.0089 to 0.038 cm).

Hot water treated molding devices may then be 15 utilized to blow mold the expander members of the present invention. Tubing of the desired material and having a required size and thickness is inserted into a balloon processing mold and heated to a temperature of from about 200-212°F (93-100°C). Weight may be added to the mold as 20 desired. The tubing is subjected to longitudinal tension and high-pressure nitrogen 380-500 psi is introduced into the tubing in the mold. The mold remains in a hot water bath for a predetermined period of time of from about 10-45 seconds, preferably 25 seconds. The mold is then 25 removed and placed in a cooling pot for a predetermined period of time of from about 20-40 seconds, preferably 30 seconds, after which the mold may be opened and the balloon removed.

In an alternative process, the balloons are formed 30 in balloon blow molding machines. The tubing is inserted

into the mold and the ends of the tubing secured into mold gaskets. The tubing is thereafter heated in the range of 190-220°F (87-104°C) for about 10 to 45 seconds, preferably 25-30 seconds, and the heated tubing is
5 subjected to longitudinal tension and expanded 1-2 times its length in the axial direction. The stretched tubing is pressurized with nitrogen in the range of about 350-500 psi and heat treated in the mold for about 10-20 seconds at about 250-280°F (121-138°C), preferably about
10 260-270°F (127-132°C). The mold is then cooled to room temperature and allowed to set at room temperature in the mold under pressure for approximately 10 to 15 seconds. Thereafter, the system can be depressurized and the balloon removed from the mold.

15

Examples

Balloons were made of polyesteretheramide block copolymer and then tested to determine certain characteristics.

Examples 1-180

20. 180 balloons were made according to the following process:

Parisons of 100 weight percent polyesteretheramide block copolymer were extruded. The parisons had inside diameters of about .015 inches to about .023 inches, wall
25 thicknesses of about .006 inches to about .010 inches, and lengths of about 18 inches.

The parisons were placed in the mold apparatus illustrated in FIGS. 2 and 3. As shown in FIG. 2, the balloon form 8 had a void 10 corresponding to the final
30 shape of the expander member. The void was made up by a

proximal form 24, a body form 26, and a distal form 28. With reference to FIG. 3, the distal end of the parison was inserted into the proximal end 14 of the mold apparatus 12, and pushed through the proximal form 24, 5 the body form 26, and the distal form 28 until it exited the distal end 16 of the mold section. Cap 18 was then placed over the distal end 16 of the apparatus 12 thereby clamping and sealing the distal end of the parison. The mold was then placed in a handle 20 such that the 10 proximal end of the parison freely extended from the handle 20. Weights 22 were then placed over the proximal end of the parison and onto the mold.

The open proximal end of the parison was then connected to a pressurized nitrogen source by a Touhy 15 Borst clamp. The nitrogen source was capable of achieving maximum pressures of 1,000 psi. The nitrogen source was then opened to varying degrees of between 350-500 psi and the mold was placed in a bath of hot water (212°F). The hot water bath warmed the parison. The 20 freely extending proximal end of the parison was held by hand such that only about the distal form 28 was under water, until the mold dropped due to longitudinal stretching and the distal end of the parison expanded radially (about 15-30 seconds). Still holding the mold 25 by hand, the mold continued to drop until it was entirely under water and the proximal end of the balloon expanded radially (about an additional 1-10 seconds).

The mold was then removed from the hot water bath and placed in a cold water bath of about 60-75°F for

about 30 seconds. The nitrogen was then shut off, and the balloon was removed from the mold.

The balloons were tested by attaching the balloons to a pressurized nitrogen source in a 37°C water bath,

5 expanding the balloons under several predetermined pressures of nitrogen (50 psi, 100 psi, 150 psi, and burst pressure), and then measuring several dimensions and the burst pressure of the balloons. Dimensions were measured with a snap gauge.

10 Tables 1-18 below list certain parameters of the process utilized to make the subject balloons (hot pot temperature, cold pot temperature, weight added to mold, and nitrogen pressure). The tables also show results of the testing of the expander members. K stat was
15 calculated as follows: (Burst pressure) - ((K Stat) (Burst Pressure Standard Deviation)). Hoop stress was calculated as follows: (Balloon Burst Pressure) (Balloon Diameter)/(2) (Balloon Wall Thickness).

Table 1

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212°F.
 COLD POT: ROOM TEMP.
 WEIGHT: 250 GRAMS
 NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
1	0.001250	0.001300	0.001250	.017x.031	0.1120	0.1200	0.1260	255
2	0.001350	0.001300	0.001300	.017x.031	0.1120	0.1200	0.1250	266
3	0.001400	0.001300	0.001300	.017x.031	0.1125	0.1210	0.1250	269
4	0.001300	0.001400	0.001250	.017x.031	0.1120	0.1200	0.1250	270
5	0.001350	0.001400	0.001300	.017x.031	0.1130	0.1200	0.1260	270
6	0.001350	0.001400	0.001300	.017x.031				
7	0.001350	0.001400	0.001300	.017x.031				
8	0.001300	0.001400	0.001300	.017x.031				
9	0.001300	0.001350	0.001300	.017x.031				
10	0.001350	0.001450	0.001300	.017x.031				
Average	0.001330	0.001370	0.001290	.017x.031	0.11230	0.12020	0.12540	266.8
Standard	4.2164E-05	5.37484E-05	2.10819E-05	0.000447	0.000447	0.000548	7.9693859	

Calculated K-stat (psi): 225.3353
 Calculated Hoop Stress (psi): 24112

Table 2

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 300 GRAMS
 NITROGEN 480 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
11	0.00190	0.00190	0.00190	.015X.035	0.1080	0.1180	0.1230	300
12	0.00180	0.00185	0.00180	.015X.035	0.1090	0.1180	0.1220	275
13	0.00170	0.00185	0.00185	.015X.035	0.1090	0.1180	0.1220	296
14	0.00180	0.00180	0.00180	.015X.035	0.1075	0.1170	0.1220	285
15	0.00190	0.00195	0.00170	.015X.035	0.1080	0.1180	0.1220	285
16	0.00180	0.00185	0.00160	.015X.035				285
17	0.00180	0.00180	0.00180	.015X.035				300
18	0.00190	0.00185	0.00170	.015X.035				293
19	0.00185	0.00180	0.00165	.015X.035				315
20	0.00170	0.00170	0.00170	.015X.035				285
Average	0.001815	0.001835	0.00173	.015X.035	0.1083	0.1178	0.1222	291.9
Standard	7.47E-05	6.687E-05	9.18937E-05		0.000671	0.000447	0.000447	11.34754

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

232.8587
 28594

Table 3

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.

COLD POT: ROOM TEMP.

WEIGHT: 250 GRAMS

NITROGEN 440 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
21	0.00170	0.00170	0.00170	.017X.034	0.110	0.121	0.125	293
22	0.00160	0.00160	0.00160	.017X.034	0.111	0.120	0.126	270
23	0.00170	0.00170	0.00170	.017X.034	0.111	0.120	0.125	293
24	0.00170	0.00170	0.00170	.017X.034	0.110	0.121	0.125	293
25	0.00160	0.00160	0.00160	.017X.034	0.110	0.121	0.125	291
26	0.00155	0.00150	0.00150	.017X.034	0.110	0.121	0.125	293
27	0.00170	0.00170	0.00170	.017X.034	0.110	0.121	0.125	283
28	0.00160	0.00160	0.00160	.017X.034	0.110	0.121	0.125	293
29	0.00170	0.00170	0.00170	.017X.034	0.110	0.121	0.125	293
30	0.00170	0.00170	0.00170	.017X.034	0.110	0.121	0.125	287
Average	0.001655	0.001650	0.001650	.017X.034	0.11040	0.12060	0.12520	288.9
Standard	5.99E-05	7.071E-05	7.07107E-05		0.000548	0.000548	0.000447	7.460265

Calculated K-stat (psi): 250.0842
 Calculated Hoop Stress (psi): 21052

Table 4

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 300 GRAMS
 NITROGEN 320 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
31	0.00140	0.00140	0.00140	.020X.032	0.117	0.123	0.128	0.128	251
32	0.00140	0.00140	0.00140	.020X.032	0.117	0.123	0.129	0.129	249
33	0.00125	0.00125	0.00125	.020X.032	0.117	0.123	0.129	0.129	253
34	0.00135	0.00130	0.00130	.020X.032	0.116	0.123	0.129	0.129	251
35	0.00140	0.00130	0.00130	.020X.032	0.116	0.123	0.129	0.129	253
36	0.00140	0.00140	0.00135	.020X.032	0.116	0.123	0.128	0.128	253
37	0.00140	0.00135	0.00135	.020X.032					243
38	0.00130	0.00130	0.00130	.020X.032					223
39	0.00135	0.00135	0.00135	.020X.032					253
40	0.00135	0.00135	0.00125	.020X.032					223
Average	0.001360	0.00134	0.0013100	.020X.032	0.1166	0.123	0.1286	0.1286	245.2
Standard	5.16E-05	5.164E-05	7.37865E-05		0.000548	1.86E-09	0.000548	0.000548	12.0904

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

182.2936
 22176

Table 5

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 350 GRAMS
 NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (Inches)	Double Proximal Wall Thickness (Inches)	Double Distal Wall Thickness (Inches)	Measured ID/OD (Inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
41	0.00160	0.00160	0.00160	.020X.035	0.115	0.125	0.130	253
42	0.00170	0.00170	0.00170	.020X.035	0.117	0.125	0.130	263
43	0.00160	0.00170	0.00170	.020X.035	0.117	0.125	0.130	269
44	0.00140	0.00150	0.00150	.020X.035	0.118	0.126	0.131	253
45	0.00145	0.00155	0.00150	.020X.035	0.114	0.123	0.129	250
46	0.00160	0.00160	0.00160	.020X.035				269
47	0.00150	0.00150	0.00140	.020X.035				268
48	0.00140	0.00140	0.00140	.020X.035				239
49	0.00150	0.00150	0.00150	.020X.035				257
50	0.00150	0.00150	0.00150	.020X.035				257
Average	0.001525	0.001555	0.001540	.020X.035	0.1162	0.1248	0.13	257.8
Standard	9.79E-05	9.56E-05	0.000107497		0.001643	0.001095	0.000707	9.681598

Calculated K-stat (psi):
 207.4266
 21097

Calculated Hoop Stress (psi):
 9637240A1_I_>

Table 6

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 200° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 250 GRAMS
 NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
51	0.00165	0.00165	0.0016	.023X.035	0.118	0.127	0.136	223
52	0.00130	0.00130	0.0013	.023X.035	0.118	0.130	0.138	223
53	0.00130	0.00140	0.0013	.023X.035	0.117	0.127	0.135	223
54	0.00140	0.00140	0.0014	.023X.035	0.118	0.128	0.136	239
55	0.00150	0.00160	0.0016	.023X.035	0.118	0.127	0.136	239
56	0.00150	0.00150	0.0015	.023X.035	0.118	0.127	0.136	239
57	0.00140	0.00140	0.0014	.023X.035	0.118	0.127	0.136	250
58	0.00130	0.00130	0.0013	.023X.035	0.118	0.127	0.136	250
59	0.00130	0.00130	0.0013	.023X.035	0.118	0.127	0.136	238
60	0.00130	0.00130	0.0013	.023X.035	0.118	0.127	0.136	253
Average	0.001395	0.001415	0.0014	.023X.035	0.1178	0.1278	0.1362	239.3
Standard	0.000121	0.0001292	0.000124722		0.000447	0.001304	0.001095	10.27456

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

185.8414
 21922

Table 7

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 350 GRAMS
 NITROGEN 420 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
61	0.00150	0.00150	0.0015	.023X.038	0.118	0.126	0.134	253
62	0.00150	0.00150	0.0015	.023X.038	0.119	0.126	0.135	253
63	0.00160	0.00160	0.0016	.023X.038	0.121	0.130	0.138	260
64	0.00160	0.00160	0.0016	.023X.038	0.120	0.127	0.138	245
65	0.00140	0.00140	0.0014	.023X.038	0.120	0.127	0.139	253
66	0.00160	0.00160	0.0015	.023X.038				
67	0.00160	0.00160	0.0016	.023X.038				
68	0.00160	0.00160	0.0016	.023X.038				
69	0.00170	0.00170	0.0017	.023X.038				
70	0.00145	0.00145	0.0015	.023X.038				
Average	0.001555	0.001555	0.00155	.023X.038	0.1196	0.1272	0.1368	254.4
Standard	8.96E-05	8.96E-05	8.499837E-05		0.00114	0.001643	0.002168	4.926121

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

228.7694
 20810

Table 8

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 250 GRAMS
 NITROGEN 460 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
71	0.00145	0.00155	0.00155	.017X.034	0.1110	0.1119	0.1123	0.1123	305
72	0.00150	0.00150	0.00150	.017X.034	0.1100	0.120	0.120	0.124	307
73	0.00145	0.00150	0.00155	.017X.034	0.1100	0.1100	0.1100	0.1118	307
74	0.00140	0.00150	0.00150	.017X.034	0.1100	0.1100	0.1100	0.1118	307
75	0.00145	0.00155	0.00150	.017X.034	0.1100	0.120	0.120	0.123	307
76	0.00160	0.00150	0.00150	.017X.034	0.1100	0.1100	0.1100	0.1118	307
77	0.00150	0.00140	0.00145	.017X.034	0.1100	0.1100	0.1100	0.1118	307
78	0.00140	0.00140	0.00140	.017X.034	0.1100	0.1100	0.1100	0.1118	307
79	0.00150	0.00150	0.00150	.017X.034	0.1100	0.120	0.120	0.123	307
80	0.00150	0.00150	0.00150	.017X.034	0.1100	0.1100	0.1100	0.1118	307
Average	0.001475	0.00149	0.001495	.017X.034	0.1102	0.1119	0.11234	0.11234	307.1
Standard	5.89E-05	5.164E-05	4.37798E-05	0.000447	0.001	0.000548	11.74214	11.74214	

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

246.0057
 24776

Table 9

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 205° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 250 GRAMS
 NITROGEN 380 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
81	0.00115	0.00115	0.00115	.020X.032	0.114	0.120	0.125	270
82	0.00125	0.00125	0.00115	.020X.032	0.113	0.120	0.125	270
83	0.00130	0.00130	0.00120	.020X.032	0.114	0.120	0.125	270
84	0.00120	0.00120	0.00110	.020X.032	0.113	0.120	0.125	270
85	0.00120	0.00120	0.00115	.020X.032	0.115	0.121	0.126	270
85	0.00115	0.00115	0.00110	.020X.032				250
87	0.00115	0.00120	0.00110	.020X.032				271
88	0.00115	0.00120	0.00115	.020X.032				270
89	0.00125	0.00120	0.00120	.020X.032				270
90	0.00120	0.00115	0.00115	.020X.032				269
Average	0.0012	0.0012	0.001145	.020X.032	0.1138	0.1202	0.1252	268
Standard	5.27E-05	4.714E-05	3.68932E-05		0.000837	0.000447	0.000447	6.342099

Calculated K-stat (psi):

Calculated Hoop Stress (psi):

235.0021

26844

Table 10

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 250 GRAMS
 NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
91	0.00130	0.00135	0.00140	.020X.035	0.109	0.119	0.125	295
92	0.00130	0.00135	0.00140	.020X.035	0.115	0.124	0.128	300
93	0.00130	0.00135	0.00130	.020X.035	0.115	0.122	0.127	289
94	0.00130	0.00135	0.00130	.020X.035	0.113	0.124	0.130	298
95	0.00130	0.00140	0.00130	.020X.035	0.115	0.124	0.128	283
96	0.00135	0.00135	0.00135	.020X.035				
97	0.00140	0.00140	0.00140	.020X.035				
98	0.00140	0.00140	0.00140	.020X.035				
99	0.00140	0.00130	0.00140	.020X.035				
100	0.00130	0.00130	0.00130	.020X.035				
Average	0.001335	0.001355	0.001355	.020X.035	0.1134	0.1226	0.1276	293.6
Standard	4.74E-05	3.689E-05	4.97214E-05		0.002608	0.002191	0.001817	5.337498

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):
 265.829
 26962

Table 11

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 350 GRAMS
 NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
101	0.0014	0.0014	0.00140	.023X.035	0.115	0.121	0.127	298
102	0.0013	0.0013	0.00125	.023X.035	0.117	0.126	0.134	253
103	0.0013	0.0013	0.00120	.023X.035	0.117	0.126	0.131	275
104	0.0013	0.0013	0.00130	.023X.035	0.118	0.126	0.132	238
105	0.0013	0.0013	0.00140	.023X.035	0.116	0.127	0.133	281
106	0.0013	0.0013	0.00140	.023X.035				280
107	0.0013	0.0013	0.00140	.023X.035				269
108	0.0012	0.0012	0.00130	.023X.035				280
109	0.0012	0.0012	0.00125	.023X.035				283
110	0.0012	0.0012	0.00125	.023X.035				283
Average	0.00128	0.00128	0.001315	.023X.035	0.1166	0.1252	0.1314	274
Standard	6.32E-05	6.325E-05	7.83511E-05		0.00114	0.002387	0.002702	17.06849

Calculated K-stat (psi): 185.1926
 Calculated Hoop Stress (psi): 26800

Table 12

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 350 GRAMS
 NITROGEN 420 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured IDOD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
111	0.00150	0.0015	0.0014	.023X.038	0.119	0.125	0.130	310
112	0.00160	0.0016	0.0016	.023X.038	0.118	0.125	0.130	300
113	0.00160	0.0016	0.0016	.023X.038	0.118	0.125	0.130	293
114	0.00150	0.0015	0.0015	.023X.038	0.118	0.126	0.131	283
115	0.00150	0.0015	0.0015	.023X.038	0.119	0.125	0.130	280
116	0.00150	0.0016	0.0015	.023X.038				300
117	0.00145	0.0015	0.0015	.023X.038				310
118	0.00160	0.0016	0.0016	.023X.038				298
119	0.00150	0.0015	0.0015	.023X.038				298
120	0.00145	0.0015	0.0015	.023X.038				313
Average	0.00152	0.00154	0.00152	.023X.038	0.1184	0.1252	0.1302	298.5
Standard	5.87E-05	5.164E-05	6.32456E-05		0.000548	0.000447	0.000447	11.01766

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

241.1751
 24586

Table 13

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 300 GRAMS
 NITROGEN 460 PSI

Balloon No.	Double Centrwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
121	0.00110	0.00120	0.00110	.017x.031	0.108	0.116	0.120	330
122	0.00120	0.00135	0.00120	.017x.031	0.106	0.115	0.119	345
123	0.00130	0.00140	0.00135	.017x.031	0.106	0.116	0.120	300
124	0.00130	0.00130	0.00120	.017x.031	0.106	0.116	0.120	345
125	0.00130	0.00130	0.00125	.017x.031	0.108	0.116	0.120	360
126	0.00135	0.00130	0.00120	.017x.031				345
127	0.00145	0.00130	0.00130	.017x.031				375
128	0.00130	0.00130	0.00130	.017x.031				330
129	0.00145	0.00130	0.00140	.017x.031				300
130	0.00140	0.00140	0.00135	.017x.031				345
Average	0.001315	0.001315	0.001265	.017x.031	0.10680	0.11580	0.11980	337.5
Standard	0.000108	5.798E-05	9.14391E-05		0.001095	0.000447	0.000447	23.71708

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

214.1
 29720

Table 14

PEBAX GRADE: 7233
BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 212° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 350 GRAMS
 NITROGEN 500 PSI

Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
0.00150	0.00150	0.0015	.017X.034	0.11	0.116	0.121	303
0.00160	0.00160	0.0016	.017X.034	0.11	0.116	0.121	280
0.00160	0.00160	0.0016	.017X.034	0.11	0.116	0.121	353
0.00155	0.00155	0.0015	.017X.034	0.11	0.117	0.120	340
0.00160	0.00160	0.0016	.017X.034	0.11	0.116	0.121	348
0.00160	0.00160	0.0016	.017X.034	0.11	0.116	0.121	338
0.00160	0.00160	0.0016	.017X.034	0.11	0.116	0.121	350
0.00170	0.00170	0.0017	.017X.034	0.11	0.117	0.120	369
0.00170	0.00170	0.0017	.017X.034	0.11	0.116	0.121	318
0.00170	0.00170	0.0017	.017X.034	0.11	0.116	0.121	353
Average	0.001615	0.001615	0.00161	.017X.034	0.11	0.1162	0.1208
Standard	6.69E-05	6.687E-05	7.37865E-05		0.0	0.000447	0.000447
							335.2
							27.01769

Calculated K-stal (psi): 194.627
 Calculated Hoop Stress (psi): 24117

Table 15

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 210° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 350 GRAMS
 NITROGEN 400 PSI

Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured IDOD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
0.00140	0.00140	0.00140	.020X.035	0.112	0.120	0.125	359
0.00140	0.00150	0.00150	.020X.035	0.112	0.118	0.125	325
0.00140	0.00150	0.00150	.020X.035	0.113	0.118	0.123	329
0.00150	0.00150	0.00150	.020X.035	0.111	0.120	0.123	359
0.00150	0.00150	0.00150	.020X.035	0.113	0.120	0.124	350
0.00150	0.00150	0.00160	.020X.035				330
0.00140	0.00130	0.00130	.020X.035				343
0.00155	0.00155	0.00155	.020X.035				353
0.00150	0.00150	0.00150	.020X.035				309
							343
Average	0.00146	0.001485	0.001485	.020X.035	0.1122	0.1192	0.124
Standard	5.68E-05	8.182E-05	8.18196E-05		0.000837	0.001095	0.001
							16.38427

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

254.7526
 27.018

Table 16

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT: 205° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 320 GRAMS
 NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
151	0.0013	0.00125	0.001250	.020X.032	0.114	0.119	0.123	357
152	0.0013	0.00135	0.001300	.020X.032	0.113	0.119	0.123	359
153	0.0013	0.00120	0.001200	.020X.032	0.113	0.119	0.123	359
154	0.0012	0.00125	0.001200	.020X.032	0.112	0.119	0.123	369
155	0.0013	0.00120	0.001200	.020X.032	0.113	0.118	0.123	353
156	0.0012	0.00125	0.001250	.020X.032				343
157	0.0014	0.00135	0.001350	.020X.032				359
158	0.0013	0.00130	0.001300	.020X.032				359
159	0.0012	0.00120	0.001150	.020X.032				361
160	0.0013	0.00130	0.001250	.020X.032				313
Average	0.00126	0.001265	0.001245	.020X.032	0.113	0.1188	0.12300	353.2
Standard	4.9721E-05	5.798E-05	5.98609E-05		0.000707	0.000447	1.86E-09	15.56205

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

272.2306
 33342

Table 17

PEBAX GRADE: 7233**BALLOON DIMENSIONS (diameter x length): 3 x 20 mm****PARAMETERS:**

HOT POT: 210° F.
 COLD POT: ROOM TEMP.
 WEIGHT: 380 GRAMS
 NITROGEN 400 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Diameter (inches)	Burst Pressure (psi)
161	0.00140	0.00140	0.00140	.023X.035	0.116	0.122	0.126	0.122	329
162	0.00150	0.00150	0.00140	.023X.035	0.116	0.122	0.127	0.127	329
163	0.00140	0.00140	0.00150	.023X.035	0.116	0.123	0.128	0.128	330
164	0.00140	0.00140	0.00150	.023X.035	0.116	0.123	0.128	0.128	330
165	0.00135	0.00135	0.00135	.023X.035	0.117	0.124	0.129	0.129	343
166	0.00140	0.00140	0.00140	.023X.035					300
167	0.00140	0.00140	0.00150	.023X.035					345
168	0.00140	0.00140	0.00140	.023X.035					329
169	0.00140	0.00140	0.00140	.023X.035					330
170	0.00140	0.00140	0.00140	.023X.035					330
Average	0.001405	0.001405	0.001425	.023X.035	0.1162	0.1228	0.1276	0.1276	323.5
Standard	3.69E-05	3.689E-05	5.40062E-05		0.000447	0.000837	0.00114	0.00114	22.29723

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

207.4875
 28274

Table 18

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

HOT POT:
COLD POT: ROOM TEMP.
WEIGHT: 350 GRAMS
NITROGEN 420 PSI

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
171	0.00160	0.00160	0.001550	.023X.038	0.114	0.120	0.126	375
172	0.00160	0.00160	0.001600	.023X.038	0.115	0.122	0.126	300
173	0.00165	0.00160	0.001500	.023X.038	0.119	0.125	0.128	298
174	0.00160	0.00165	0.001600	.023X.038	0.116	0.122	0.127	328
175	0.00160	0.00160	0.001600	.023X.038	0.116	0.123	0.126	343
176	0.00170	0.00170	0.001700	.023X.038				370
177	0.00160	0.00170	0.001600	.023X.038				370
178	0.00170	0.00170	0.001700	.023X.038				355
179	0.00165	0.00170	0.001650	.023X.038				358
180	0.00170	0.00170	0.001700	.023X.038				373
Average	0.00164	0.001655	0.00162	.023X.038	0.116	0.1224	0.1266	347
Standard	4.59E-05	4.972E-05	6.74949E-05	0.001871	0.001817	0.000894	29.23088	

Calculated K-stat (psi):
Calculated Hoop Stress (psi):

194.9117
25898

Examples 181-206

26 balloons were made according to the process described for Examples 1-180, except that the mold apparatus did not utilize weights 22 separately, but 5 rather incorporated a preselected weight into handle 20.

The balloons were tested to measure distension and balloon burst strength. Distension is defined as the ratio of two balloon diameters. In this test, a balloon was inflated to a series of pressures. The diameter was 10 measured at each pressure. The distension is the ratio of the diameter at the lowest pressure to the diameter at the highest pressure. Inflation was performed at 1 bar increments up to burst pressure.

To test the balloons, the balloons were first placed 15 in temperature controlled water bath, and warmed for a minimum of 1 minute in water. The balloons were then attached to a pneumatic inflation/deflation device. A vacuum was created. Starting with a 4 bar pressure for 20 seconds, the balloon diameter and length were 20 measured. The balloons were deflated, and the measurements were recorded. Increasing the pressure by 1 bar, the balloon diameters and lengths were measured. This procedure was repeated until the balloons bursted. The burst pressure and the type of burst profile were 25 recorded.

Tables 19-21 below show the results of the testing of the expander members.

PEBAX GRADE 7233
 Tubing Dimensions (ID x OD): 0.48 x 0.81 mm
 Balloon Dimensions (OD x length): 3.0 x 20 mm
 Diameter Form: 3.00 mm

Table 19

	DIAMETER (mm)								Average
	Balloon Number								
alm	181	182	183	184	185	186	187	188	190
4	2.57	2.60	3	2.60	2.57	2.55	2.54	2.61	2.57
6	2.79	2.81	3	2.81	2.79	2.79	2.70	2.75	2.78
8	2.91	2.94	3	2.93	2.93	2.95	2.89	2.88	2.93
10	3.01	3.01	3	3.02	3.02	3.01	2.99	3.00	3.00
12	3.06	3.07	3	3.08	3.09	3.08	3.03	3.05	3.06
14	3.12	3.14	3	3.13	3.12	3.12	3.09	3.11	3.12
16	3.17	3.17	3	3.17	3.18	3.17	3.14	3.16	3.16
18	3.23	3.24	3	3.25	3.24	3.23	3.21	3.22	3.23

Average burst pressure
 Minimum burst pressure
 Maximum burst pressure

21.1 atm
 20.0 atm
 22.0 atm

Table 20

PEBAX GRADE 7233

Tubing Dimensions (ID x OD): 0.48 x 0.82 mm

Balloon Dimensions (OD x length): 3.0 x 20 mm

Diameter Form: 3.25 mm

	DIAMETER (mm)					Average
	Balloon Number					
atm	191	192	193	194	195	196
4	2.73	2.74	2.66	2.71	2.69	2.71
6	2.97	2.93	2.89	2.92	2.92	2.94
8	3.12	3.06	3.03	3.08	3.06	3.07
10	3.18	3.12	3.15	3.16	3.12	3.17
12	3.23	3.20	3.22	3.23	3.19	3.23
14	3.30	3.27	3.27	3.27	3.25	3.28
16	3.33	3.31	3.31	3.30	3.29	3.32
18	3.39	3.33	3.37	3.37	3.36	3.40

Average burst pressure
 Minimum burst pressure
 Maximum burst pressure

21.4 atm
 20.0 atm
 22.0 atm

Table 21

PEBAX GRADE 7233

Tubing Dimensions (ID x OD): 0.65 x 0.90 mm
 Balloon Dimensions (OD x length): 3.0 x 20 mm
 Diameter Form: 3.25 mm

atm	Balloon Number						Average
	199	200	201	202	203	204	
4	2.91	2.92	2.94	2.91	2.87	2.85	2.93
6	3.17	3.15	3.16	3.13	3.14	3.10	3.17
8	3.28	3.32	3.29	3.29	3.28	3.25	3.31
10	3.40	3.44	3.41	3.39	3.40	3.36	3.42
12	3.52	3.52	3.49	3.52	3.51	3.48	3.48
14	3.66	3.65	3.64	3.64	3.65	3.65	3.62
16	3.79	3.79	3.82	3.83	3.80	3.78	3.82
18	4.05	-	-	-	4.06	4.08	4.05
					4.17		4.08

Average burst pressure 19.3 atm
 Minimum burst pressure 18.0 atm
 Maximum burst pressure 20.0 atm

Examples 207-236

30 balloons were made according to the procedure described above for Examples 1-180, except that parisons had inside diameters of about .025 inches and wall 5 thicknesses of about .0065 inches.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16 atms, and then the balloons were burst.

10 Tables 22-28 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

BALLOON COMPLIANCE

Table 22

PEBAX Grade: 7233
Dimensions (dia. x lgl.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure	DIAMETER (inches)				
	atm	psi	.207	.208	.209
4	58.8	.111	.111	.112	.112
5	73.5	.113	.114	.115	.114
6	88.2	.116	.116	.117	.116
7	102.5	.118	.117	.118	.117
8	117.6	.119	.119	.119	.118
9	132.3	.120	.120	.120	.119
10	147.0	.122	.121	.121	.120
11	161.7	.122	.122	.122	.121
12	176.4	.123	.123	.123	.122
13	191.1	.124	.124	.124	.123
14	205.8	.125	.125	.125	.124
15	220.5	.126	.126	.125	.125
16	235.2	.127	.127	.126	.126
					.125
					.127
Burst Pressure (psi)	278	249	278	307	291
Direction of Burst	Axial	Axial	Axial	Axial	Axial

BALLOON COMPLIANCE

Table 23

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure atm	psi	DIAMETER (inches)			
		212	213	214	215
4	58.8	.113	.113	.111	.112
5	73.5	.115	.115	.114	.114
6	88.2	.117	.117	.116	.116
7	102.5	.118	.118	.118	.118
8	117.6	.119	.119	.119	.119
9	132.3	.120	.120	.120	.120
10	147.0	.121	.121	.121	.121
11	161.7	.122	.122	.122	.122
12	176.4	.123	.123	.123	.123
13	191.1	.124	.124	.124	.124
14	205.8	.125	.125	.125	.125
15	220.5	.126	.126	.126	.126
16	235.2	.127	.127	.127	.127
Burst Pressure (psi)		266	264	280	280
Direction of Burst		Axial	Axial	Axial	Axial

Table 24
BALLOON COMPLIANCE

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.): 15

Pressure atm	psi	DIAMETER (inches)			
		217	218	219	220
4	58.8	.109	.110	.110	.109
5	73.5	.112	.114	.114	.112
6	88.2	.114	.116	.115	.114
7	102.5	.116	.117	.117	.116
8	117.6	.117	.119	.118	.118
9	132.3	.119	.119	.120	.119
10	147.0	.120	.120	.121	.120
11	161.7	.121	.121	.122	.121
12	176.4	.122	.122	.123	.122
13	191.1	.123	.124	.124	.123
14	205.8	.124	.125	.125	.124
15	220.5	.125	.126	.126	.125
16	235.2	.125	.127	.127	.126
Burst Pressure (psi)		290	250	250	250
Direction of Burst		Axial	Axial	Axial	Axial

BALLOON COMPLIANCE					
PEBAX Grade:	7233	Dimensions (dia. x lgt.):	3.0 x 20 mm	Cone Angle:	10 degrees
Rated Burst:	176 psi	Hold (Secs.)	15		

Pressure atm	psi	DIAMETER (inches)			
		222	223	224	225
4	58.8	.108	.111	.111	.110
5	73.5	.110	.114	.114	.113
6	88.2	.112	.116	.116	.115
7	102.5	.114	.118	.117	.117
8	117.6	.116	.119	.118	.118
9	132.3	.117	.120	.120	.119
10	147.0	.119	.121	.121	.120
11	161.7	.120	.122	.122	.121
12	176.4	.121	.123	.123	.122
13	191.1	.122	.124	.124	.123
14	205.8	.123	.125	.125	.124
15	220.5	.124	.126	.126	.125
16	235.2	.125	.127	.127	.126
Burst Pressure (psi)		264	280	260	280
Direction of Burst		Axial	Axial	Axial	Axial

Table 26
BALLOON COMPLIANCE

PEBAX Grade: 7233
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 10 degrees
 Rated Burst: 176 psi
 Hold (Secs.) 15

Pressure atm	psi	DIAMETER (Inches)				
		227	228	229	230	231
4	58.8	.111	.111	.110	.111	.110
5	73.5	.113	.114	.113	.113	.113
6	88.2	.115	.116	.114	.115	.115
7	102.5	.117	.118	.116	.117	.117
8	117.6	.119	.119	.118	.118	.118
9	132.3	.120	.120	.119	.119	.119
10	147.0	.121	.121	.120	.120	.120
11	161.7	.122	.122	.121	.121	.121
12	176.4	.123	.123	.123	.122	.122
13	191.1	.123	.124	.124	.123	.123
14	205.8	.124	.125	.125	.124	.124
15	220.5	.125	.126	.126	.125	.125
16	235.2	.126	.127	.127	.126	.126
Burst Pressure (psi)	278	280	265	260	260	
Direction of Burst	Axial	Axial	Axial	Axial	Axial	Axial

Table 27
BALLOON COMPLIANCE

PEBAX Grade: 7233
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.) 15

Pressure atm	psi	DIAMETER (Inches)				
		232	233	234	235	236
4	58.8	.111	.111	.110	.111	.112
5	73.5	.114	.114	.113	.114	.115
6	88.2	.116	.116	.116	.116	.1165
7	102.5	.117	.117	.117	.117	.118
8	117.8	.119	.190	.118	.1185	.119
9	132.3	.120	.120	.119	.120	.120
10	147.0	.121	.121	.1205	.121	.121
11	161.7	.122	.122	.122	.122	.122
12	176.4	.1225	.123	.123	.123	.123
13	191.1	.124	.124	.124	.124	.124
14	205.8	.124	.125	.125	.125	.125
15	220.5	.125	.126	.125	.126	.126
16	235.2	.126	.127	.126	.127	.127
Burst Pressure (psi)		265	280	305	278	260
Direction of Burst		Axial	Axial	Axial	Axial	Axial

Table 28
**BALLOON COMPLIANCE
 MEASUREMENTS BEFORE TESTING**

	Double Wall Thickness Measurements		
	Proximal Side-Body	Center	Distal Side-Body
207	.00175	.00120	.00135
208	.00145	.00140	.00120
209	.00130	.00140	.00140
210	.00140	.00150	.00140
211	.00165	.00175	.00185
212	.00135	.00120	.00125
213	.00150	.00140	.00120
214	.00135	.00120	.00115
215	.00155	.00130	.00120
216	.00135	.00120	.00125
217	.00140	.00135	.00145
218	.00165	.00130	.00125
219	.00145	.00135	.00130
220	.00155	.00120	.00140
221	.00135	.00120	.00120
222	.00155	.00135	.00140
223	.00140	.00130	.00135
224	.00145	.00135	.00120
225	.00160	.00135	.00125
226	.00150	.00135	.00130
227	.00155	.00135	.00135
228	.00155	.00150	.00135
229	.00150	.00135	.00130
230	.00135	.00135	.00120
231	.00160	.00135	.00130
232	.00160	.00135	.00130
233	.00140	.00120	.00120
234	.00145	.00135	.00125
235	.00150	.00145	.00120
236	.00145	.00135	.00125

Examples 237-266

30 balloons were made according to the procedure described above for Examples 1-180.

The balloons were tested according to the procedure 5 described above for Examples 1-180, except that balloons were tested at 1 atm increments from 4-16 atm and then burst.

Tables 29-35 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time 10 representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 29
BALLOON COMPLIANCE

PEBAX Grade: 6333
Dimensions (dia. x lgt.): 3.0 x 20 mm
Cone Angle: 10 degrees
Rated Burst: 176 psi
Hold (Secs.): 15

Pressure atm	psi	DIAMETER (Inches)			
		237	238	239	240
Balloon Number					
4	58.8	.114	.115	.114	.114
5	73.5	.116	.118	.117	.117
6	88.2	.118	.120	.120	.119
7	102.5	.120	.122	.121	.121
8	117.6	.122	.123	.123	.122
9	132.3	.123	.124	.124	.124
10	147.0	.125	.126	.1260	.125
11	161.7	.126	.127	.127	.126
12	176.4	.128	.129	.128	.128
13	191.1	.129	.130	.130	.129
14	205.8	.130	.132	.132	.131
15	220.5	.132	.134	.133	.132
16	235.2	.133	.135	.135	.132
				Burst	.135
Burst Pressure (psi)	268	250	250	235	250
Direction of Burst	Axial	Axial	Axial	Axial	Axial

Table 30

BALLOON COMPLIANCE

PEBAX Grade: 6333
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 10 degrees
 Rated Burst: 176 psi
 Hold (Secs.): 15

Pressure atm	psi	DIAMETER (inches)		
		242	243	244
4	58.8	.116	.115	.115
5	73.5	.119	.118	.117
6	88.2	.121	.120	.119
7	102.5	.122	.122	.121
8	117.6	.124	.124	.122
9	132.3	.125	.125	.124
10	147.0	.127	.126	.125
11	161.7	.128	.128	.126
12	176.4	.129	.129	.127
13	191.1	.131	.131	.128
14	205.8	.133	.132	.129
15	220.5	.135	.134	.131
16	235.2	.136	.135	.132
				.130
				.133
				.134
				.135
Burst Pressure (psi)	250	250	250	260
Direction of Burst	Axial	Axial	Axial	Axial

Table 31

BALLOON COMPLIANCE

PEBAK Grade: 6333
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 10 degrees
 Rated Burst: 176 psi
 Hold (Secs.) 15

Pressure atm	DIAMETER (inches)			
	psi	247	248	249
		Balloon Number		
4	58.8	.115	.114	.116
5	73.5	.118	.118	.118
6	88.2	.120	.120	.120
7	102.5	.122	.122	.122
8	117.6	.123	.123	.123
9	132.3	.125	.125	.125
10	147.0	.127	.127	.126
11	161.7	.128	.128	.128
12	176.4	.129	.130	.129
13	191.1	.131	.131	.131
14	205.8	.133	.133	.132
15	220.5	.134	.135	.134
16	235.2	.135	.136	.136
Burst Pressure (psi)	250	250	250	250
Direction of Burst	Axial	Axial	Axial	Axial

Table 32
BALLOON COMPLIANCE

PEBAX Grade: 6333
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 10 degrees
 Rated Burst: 176 psi
 Hold (Secs.): 15

Pressure atm	psi	DIAMETER (inches)			
		252	253	254	255
4	58.8	.114	.114	.115	.114
5	73.5	.116	.117	.118	.117
6	88.2	.119	.120	.120	.119
7	102.5	.121	.122	.121	.121
8	117.6	.122	.123	.122	.122
9	132.3	.124	.124	.124	.123
10	147.0	.125	.126	.125	.125
11	161.7	.126	.127	.127	.126
12	176.4	.128	.129	.129	.128
13	191.1	.130	.130	.130	.129
14	205.8	.131	.131	.131	.131
15	220.5	.133	.133	.133	.133
16	235.2	.135	.135	.135	.135
Burst Pressure (psi)		250	250	250	250
Direction of Burst		Axial	Axial	Axial	Axial

Table 33

BALLOON COMPLIANCE

PEBAK Grade: 6333
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 10 degrees
 Rated Burst: 176 psi
 Hold (Secs.) 15

Pressure atm	psi	DIAMETER (inches)			
		257	258	259	260
4	58.8	.115	.115	.114	.114
5	73.5	.118	.117	.117	.115
6	88.2	.120	.119	.119	.118
7	102.5	.121	.120	.120	.120
8	117.6	.123	.121	.121	.122
9	132.3	.124	.122	.123	.123
10	147.0	.125	.123	.124	.124
11	161.7	.127	.125	.125	.125
12	176.4	.128	.127	.127	.126
13	191.1	.129	.129	.129	.128
14	205.8	.131	.131	.130	.130
15	220.5	.132	.132	.132	.132
16	235.2	.134	.134	.134	.134
Burst Pressure (psi)		250	235	250	250
Direction of Burst		Axial	Axial	Axial	Axial

Table 34
BALLOON COMPLIANCE

PEBAX Grade: 6333
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 10 degrees
 Rated Burst: 176 psi
 Hold (Secs.) 15

Pressure atm	psi	DIAMETER (Inches)			
		262	263	264	265
4	58.8	.115	.114	.114	.115
5	73.5	.118	.117	.117	.117
6	88.2	.119	.119	.118	.118
7	102.5	.121	.120	.120	.120
8	117.6	.122	.121	.121	.121
9	132.3	.123	.124	.122	.122
10	147.0	.124	.125	.123	.124
11	161.7	.126	.127	.125	.125
12	176.4	.128	.128	.127	.127
13	191.1	.129	.130	.129	.128
14	205.8	.131	.131	.130	.129
15	220.5	.133	.133	.132	.131
16	235.2	.134	.135	.134	.133
Burst Pressure (psi)	250		268	250	250
Direction of Burst	Axial	Axial	Axial	Axial	Axial

Table 35

**BALLOON COMPLIANCE
MEASUREMENTS BEFORE TESTING**

Double Wall Thickness Measurements			
	Proximal Side-Body	Center	Distal Side-Body
237	.00155	.00130	.00120
238	.00135	.00120	.00120
239	.00125	.00120	.00110
240	.00125	.00120	.00120
241	.00130	.00120	.00120
242	.00135	.00120	.00120
243	.00130	.00115	.00110
244	.00130	.00120	.00120
245	.00135	.00125	.00110
246	.00135	.00120	.00120
247	.00135	.00120	.00110
248	.00125	.00120	.00115
249	.00120	.00120	.00115
250	.00130	.00125	.00110
251	.00130	.00120	.00110
252	.00135	.00120	.00115
253	.00130	.00120	.00105
254	.00120	.00110	.00110
255	.00120	.00115	.00110
256	.00125	.00120	.00110
257	.00125	.00120	.00110
258	.00135	.00120	.00110
259	.00135	.00120	.00110
260	.00120	.00110	.00115
261	.00130	.00125	.00110
262	.00130	.00120	.00110
263	.00125	.00120	.00115
264	.00130	.00115	.00115
265	.00135	.00120	.00110
266	.00120	.00110	.00105

Examples 267-276

10 balloons were made according to the procedure described above for Examples 1-180, except that parisons had inside diameters of about .025 inches and wall
5 thicknesses of about .0065 inches.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16 atms, and then the balloons were burst.

10 Tables 36-38 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 36

BALLOON COMPLIANCE

PEBAX Grade: 7033
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 10 degrees
 Rated Burst: 176 psi
 Hold (Secs.): 15

Pressure atm	Pressure psi	DIAMETER (inches)			
		267	268	269	270
4	58.8	.112	.113	.113	.113
5	73.5	.116	.116	.116	.116
6	88.2	.118	.118	.118	.118
7	102.5	.120	.119	.120	.119
8	117.6	.121	.120	.121	.120
9	132.3	.122	.121	.122	.121
10	147.0	.123	.122	.124	.122
11	161.7	.124	.123	.125	.124
12	176.4	.125	.125	.126	.124
13	191.1	.126	.127	.127	.125
14	205.8	.127	.1275	.128	.127
15	220.5	.128	.128	.129	.1275
16	235.2	.129	.129	.130	.1285
Burst Pressure (psi)		263	264	250	264
Direction of Burst		Axial	Axial	Axial	Axial

Table 37
BALLOON COMPLIANCE

PEBAK Grade: 7033
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 10 degrees
 Rated Burst: 176 psi
 Hold (Secs.): 15

Pressure atm	psi	DIAMETER (Inches)		
		272	273	274
4	58.8	.112	.114	.114
5	73.5	.115	.117	.116
6	88.2	.117	.118	.117
7	102.5	.1185	.120	.119
8	117.6	.121	.121	.120
9	132.3	.122	.122	.121
10	147.0	.123	.123	.120
11	161.7	.124	.124	.121
12	176.4	.126	.126	.122
13	191.1	.128	.1265	.123
14	205.8	.128	.1280	.128
15	220.5	.129	.129	.127
16	235.2	.130	.130	.128
				.129
				.129
Burst Pressure (psi)	250	264	264	264
Direction of Burst	Axial	Axial	Axial	Axial

BALLOON COMPLIANCE MEASUREMENTS BEFORE TESTING

Double Wall Thickness Measurements			
	Proximal Side-Body	Center	Distal Side-Body
267	.00110	.00110	.00105
268	.00105	.00105	.00105
269	.00105	.00100	.00100
270	.00110	.00110	.00110
271	.00115	.00110	.00100
272	.00115	.00100	.00100
273	.00115	.00110	.00100
274	.00115	.00100	.00105
275	.00110	.00110	.00100
276	.00110	.00100	.00100

Examples 277-306

30 balloons were made according to the procedure described above for Examples 1-180, except that cone angles were 267 and the parison inside diameter was .025 inches with a wall thickness of .0065.

The balloons were tested according to the procedure described above for Examples 1-180, except that outside diameters were measured at 1 atm increments from 4-16 atms, and then the balloons were burst.

Tables 39-41 below list certain parameters (PEBAX grade, dimensions, cone angle, rated burst, and hold time representing the total amount of time that the mold was held in the water). The tables also show results of the testing of the expander members.

Table 39

BALLOON COMPLIANCE

PEBAX Grade: 7033
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 26°
 Rated Burst: 176
 Hold (Secs.) 15

Pressure	DIAMETER (cm)					
	Balloon Numbers					
atm	277	278	279	280	281	282
4	2.9972	3.0226	2.9718	2.9210	2.9210	2.8448
5	3.0988	3.1242	3.0988	3.0226	2.9972	2.9972
6	3.1496	3.1750	3.1496	3.1242	3.07340	3.1496
7	3.2004	3.2258	3.2004	3.1750	3.1750	3.2258
8	3.2766	3.2512	3.2258	3.2258	3.2258	3.2258
9	3.3020	3.3020	3.2766	3.2766	3.2766	3.2512
10	3.3528	3.3528	3.3274	3.3030	3.3274	3.3020
11	3.3782	3.4036	3.3782	3.3528	3.3782	3.3528
12	3.4544	3.4544	3.4290	3.4036	3.4036	3.4036
13	3.5052	3.4798	3.5052	3.4290	3.4544	3.4544
14	3.5560	3.5560	3.5814	3.5052	3.5814	3.5052
15	3.5814	3.6068	3.6068	3.5306	3.6576	3.5560
16	3.6576	3.6830	3.6322	3.6068	3.6068	3.6322
Burst psi	290	265	265	295	260	265
atm	19.70	18.02	18.02	20.06	17.68	18.02
					17.68	17.00
						18.02

Table 40

BALLOON COMPLIANCE

PEBAK Grade: 7033
 Dimensions (dia. x lgt.): 3.0 x 20 mm
 Cone Angle: 26°
 Rated Burst: 176
 Hold (Secs.) 15

Pressure	DIAMETER (cm)					
	Balloon Numbers					
atm	287	288	289	290	291	292
4	2.8956	2.8956	2.9210	2.8702	2.8956	2.9718
5	2.9972	2.9972	3.0480	2.9972	3.0226	3.0988
6	3.1242	3.0988	3.1496	3.0988	3.1242	3.1750
7	3.2004	3.2004	3.2258	3.1496	3.1750	3.2512
8	3.2512	3.2258	3.3020	3.2258	3.2512	3.3020
9	3.3274	3.3020	3.3528	3.2766	3.3020	3.3528
10	3.3782	3.3528	3.4036	3.3274	3.3528	3.4036
11	3.4290	3.4036	3.4798	3.3782	3.4036	3.4544
12	3.4798	3.4544	3.5560	3.4290	3.4544	3.5052
13	3.5560	3.5306	3.6068	3.4798	3.5052	3.5306
14	3.6068	3.5560	3.6576	3.5306	3.5560	3.5944
15	3.6576	3.6068	3.7338	3.5814	3.6322	3.5306
16	3.7592	3.6576	3.8354	3.6576	3.7084	3.5560
Burst psi	265	265	265	265	265	265
atm	18.02	18.02	18.02	18.02	18.02	18.02

Table 41

BALLOON COMPLIANCE

PEBAX Grade:	7033
Dimensions (dia. x lgt.):	3.0 x 20 mm
Cone Angle:	26°
Rated Burst:	176
Hold (Secs.):	15

Examples 307-366

60 balloons were made according to the following procedure: Tubing was placed into a mold and preheated for 15-30 seconds to a preselected balloon blowing temperature. The tubing was stretched and inflated to make a balloon. The balloon was allowed to remain at the balloon blowing temperature for 15-30 seconds, and then elevated to at least the crystallization temperature for 10-20 seconds. The balloon was then cooled to room temperature and removed from the mold.

The balloons were tested according to the procedure described above for Examples 1-180.

Tables 42-47 below list certain parameters (PEBAX grade, dimensions, crystallization temperature, mold temperature, left and right stretch dimensions, nitrogen pressure, and air flow). The tables also show results of the testing of the expander members.

Table 42

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

TEMP:	CRYSTALLIZATION:
STRETCH:	200° F
PSI:	2.60 INCHES
AIRFLOW:	350
	200

MOLD:
RIGHT:
190° F
2.60 INCHES

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
								58
307	0.00120	0.00120	0.00130	.020x.035	0.119	0.128	0.135	238
308	0.00120	0.00130	0.00120	.020x.035	0.118	0.127	0.137	241
309	0.00135	0.00135	0.00145	.020x.035	0.118	0.128	0.136	245
310	0.00130	0.00140	0.00120	.020x.035	0.117	0.127	0.137	238
311	0.00125	0.00135	0.00145	.020x.035	0.117	0.127	0.134	240
312	0.00135	0.00125	0.00125	.020x.035				249
313	0.00125	0.00125	0.00125	.020x.035				239
314	0.00135	0.00130	0.00130	.020x.035				230
315	0.00130	0.00130	0.00130	.020x.035				240
316	0.00130	0.00130	0.00135	.020x.035				240
Average	0.001285	0.0013	0.001305	.020x.035	0.1178	0.1274	0.1358	240
Standard	5.79751E-05	5.7735E-05	8.95979E-05		0.000837	0.000548	0.001304	4.898979

Calculated K-stat (psi):
Calculated Hoop Stress (psi):

214.5106
23794.55

Table 43

PEBAX GRADE: 6333

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

TEMP: CRYSTALLIZATION: 260° F
STRETCH: LEFT: 2.75 INCHES
PSI: 350
AIRFLOW: 200

MOLD: 190° F
RIGHT: 2.75 INCHES

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter: 50 psi (inches)	Diameter: 100 psi (inches)	Diameter: 150 psi (inches)	Burst Pressure (psi)
317	0.00130	0.00135	0.00130	.020x.035	0.116	0.127	0.135	240
318	0.00135	0.00140	0.00140	.020x.035	0.114	0.127	0.135	248
319	0.00135	0.00145	0.00135	.020x.035	0.116	0.127	0.134	240
320	0.00135	0.00135	0.00145	.020x.035	0.115	0.127	0.134	251
321	0.00130	0.00145	0.00130	.020x.035	0.115	0.127	0.135	240
322	0.00145	0.00135	0.00135	.020x.035				240
323	0.00140	0.00140	0.00140	.020x.035				240
324	0.00135	0.00135	0.00140	.020x.035				248
325	0.00135	0.00135	0.00135	.020x.035				240
326	0.00135	0.00135	0.00135	.020x.035				240
Average	0.001355	0.00138	0.00137	.020x.035	0.1152	0.127	0.1346	242.7
Standard	4.38E-05	4.216E-05	4.74342E-05		0.000837	1.86E-09	0.000548	4.423423

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

219.6849
 22747.53

Table 44

P.EBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 2 x 30 mm

PARAMETERS:

TEMP:
STRETCH:
PSI:
AIRFLOW:

CRYSTALLIZATION:

LEFT:
380

200° F
2.75 INCHES

MOLD:
RIGHT:
190° F
2.75 INCHES

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter	Diameter	Diameter	Burst Pressure (psi)
					50 psi (inches)	100 psi (inches)	150 psi (inches)	
327	0.00130	0.001350	0.00130	.020x.035	0.115	0.125	0.129	270
328	0.00125	0.001300	0.00130	.020x.035	0.116	0.125	0.129	270
329	0.00130	0.001350	0.00130	.020x.035	0.116	0.125	0.132	270
330	0.00130	0.001300	0.00125	.020x.035	0.115	0.127	0.132	270
331	0.00125	0.001300	0.00130	.020x.035	0.116	0.126	0.132	263
332	0.00135	0.001350	0.00130	.020x.035	0.116	0.126	0.132	270
333	0.00135	0.001300	0.00130	.020x.035				280
334	0.00130	0.001300	0.00130	.020x.035				280
335	0.00125	0.001250	0.00120	.020x.035				270
336	0.00130	0.001200	0.00130	.020x.035				283
								240
Average	0.001295	0.0013	1.285E-03	.020x.035	0.1156	0.1256	0.1308	269.6
Standard	3.69E-05	4.714E-05	3.37474E-05		0.000548	0.000894	0.001643	12.09408

Calculated K-stat (psi):

Calculated Hoop Stress (psi):

206.6745
26148.08

Table 45

PEBAX GRADE: 7033

BALLOON DIMENSIONS (diameter x length): 3 x 30 mm

PARAMETERS:

TEMP:	CRYSTALLIZATION:
STRETCH:	LEFT:
PSI:	320
AIRFLOW:	200

**260° F
2.25 INCHES**

**210° F
2.25 INCHES**

**MOLD:
RIGHT:**

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
337	0.00100	0.00100	0.00100	.020x.035	0.121	0.13	0.138	238
338	0.00115	0.00120	0.00100	.020x.035	0.121	0.129	0.136	230
339	0.00100	0.00105	0.00115	.020x.035	0.121	0.113	0.138	220
340	0.00110	0.00115	0.00100	.020x.035	0.121	0.129	0.136	219
341	0.00105	0.00110	0.00100	.020x.035	0.121	0.129	0.137	238
342	0.00105	0.00100	0.00100	.020x.035				239
343	0.00120	0.00120	0.00105	.020x.035				238
344	0.00100	0.00110	0.00105	.020x.035				238
345	0.00100	0.00105	0.00105	.020x.035				220
346	0.00105	0.00110	0.00100	.020x.035				239
Average	0.00106	0.001095	0.00103	.020x.035	0.121	0.1294	0.137	231.9
Standard	6.99E-05	7.246E-05	4.83046E-05		0	0.000548	0.001	8.83742

Calculated K-stat (psi):
Calculated Hoop Stress (psi):

185.9189
28309.3

Table 46

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

TEMP:
STRETCH:
PSI:
AIRFLOW:

CRYSTALLIZATION:
LEFT:
400
200

400° F
2 INCHES

MOLD:
RIGHT:
190° F
2 INCHES

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
347	0.00140	0.00140	0.00140	.020x.035	0.113	0.119	0.124	305
348	.00145	0.00150	0.00145	.020x.035	0.111	0.119	0.124	330
349	0.00145	0.00150	0.00150	.020x.035	0.113	0.122	0.124	315
350	0.00140	0.00140	0.00140	.020x.035	0.115	0.122	0.125	313
351	0.00150	0.00145	0.00140	.020x.035	0.113	0.120	0.124	343
352	0.00145	0.00145	0.00135	.020x.035				343
353	0.00150	0.00150	0.00140	.020x.035				330
354	0.00140	0.00150	0.00140	.020x.035				329
355	0.00140	0.00140	0.00140	.020x.035				303
356	0.00140	0.00150	0.00140	.020x.035				313
Average	0.001433	0.00146	0.00141	.020x.035	0.113	0.1204	0.1242	246.437
Standard	4.33E-05	4.595E-05	3.94405E-05		0.001414	0.001517	0.000447	27081.6
								14.59985

Calculated K-stat (psi):
 Calculated Hoop Stress (psi):

246.437
 27081.6

Table 47

PEBAX GRADE: 7233

BALLOON DIMENSIONS (diameter x length): 3 x 20 mm

PARAMETERS:

TEMP:

STRETCH:

PSI:

AIRFLOW:
330
200

CRYSTALLIZATION:

LEFT:

260° F
2.25 INCHESMOLD:
RIGHT:
210° F
2.25 INCHES

Balloon No.	Double Centerwall Thickness (inches)	Double Proximal Wall Thickness (inches)	Double Distal Wall Thickness (inches)	Measured ID/OD (inches)	Diameter 50 psi (inches)	Diameter 100 psi (inches)	Diameter 150 psi (inches)	Burst Pressure (psi)
357	0.00110	0.00100	0.00125	.020x.035	0.118	0.125	0.128	240
358	0.00100	0.00105	0.00115	.020x.035	0.119	0.125	0.13	260
359	0.00100	0.00105	0.00120	.020x.035	0.118	0.123	0.128	242
360	0.00110	0.00120	0.00100	.020x.035	0.119	0.126	0.131	245
361	0.00110	0.00120	0.00120	.020x.035	0.119	0.125	0.13	260
362	0.00100	0.00100	0.00120	.020x.035				260
363	0.00120	0.00120	0.00130	.020x.035				260
364	0.00115	0.00105	0.00120	.020x.035				242
365	0.00100	0.00105	0.00120	.020x.035				262
366	0.00110	0.00100	0.00115	.020x.035				260
Average	0.001075	0.00108	0.001185	.020x.035	0.1186	0.1248	0.1294	191.192
Standard	7.17E-05	8.5635E-05	7.83511E-05		0.000548	0.001095	0.001342	250.2 11.34117 29046.47

Calculated K-stat (psi):
Calculated Hoop Stress (psi):

Figures 4-15 were prepared by collecting data according to material type, and reducing the data to a series of quadratic equations that include stretch, crystallization temperature, and balloon blowing
5 temperature as dependant variables. The equations were then plotted using a statistical design of experiments program called ECHIP[®]. Response variables of interest were then plotted.

With regard to Figures 4-15, the balloons were
10 expanded to two times their original length in the axial direction.

The foregoing specification and figures are presented for the purpose of illustrating, and not limiting, the present invention.

CLAIMS

1. A balloon for an angioplasty device having a single polymeric layer comprising (a) from about 20 to about 100 weight percent polyesteretheramide copolymer,
5 and (b) from about 0 to about 80 weight percent polyamide; wherein the polymeric layer contains substantially no polyetheramide having substantially no ester linkages.
2. The balloon of claim 1 wherein the
10 polyesteretheramide copolymer comprises a block copolymer.
3. The balloon of claim 1 wherein the polyesteretheramide copolymer comprises a random copolymer.
15
4. The balloon of claim 1 wherein the polyesteretheramide copolymer has a hardness of from about 45 Shore D to about 78 Shore D.
5. The balloon of claim 4 wherein the polyesteretheramide copolymer has a hardness of from
20 about 55 Shore D to about 75 Shore D.
6. The balloon of claim 5 wherein the polyesteretheramide copolymer has a hardness of from about 63 to about 72 Shore D.
7. The balloon of claim 6 wherein the
25 polyesteretheramide copolymer has a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D.
8. The balloon of claim 1 wherein the single polymeric layer comprises at least about 2 weight percent
30 polyamide.

9. The balloon of claim 8 wherein the polyamide is selected from the group consisting of nylon 12, nylon 11, nylon 6, nylon 6/6, nylon 4/6, and combinations thereof.

10. The balloon of claim 9 comprising from about 20
5 to about 80 weight percent nylon 12 and about 20 to about
80 weight percent polyetheretheramide copolymer.

11. The balloon of claim 10 comprising about 60 weight percent nylon 12 and about 40 weight percent polyetheretheramide copolymer.

10 12. The balloon of claim 9 comprising from about 25
to about 80 weight percent nylon 4/6 and about 20 to
about 75 weight percent polyetheretheramide copolymer.

13. The balloon of claim 12 comprising about 65 weight percent nylon 4/6 and about 35 weight percent
15 polyetheretheramide copolymer.

14. The balloon of claim 1 wherein the single polymeric layer further comprises at least about 2 weight percent of a polymer selected from polyester copolymer, polyurethane copolymer, polyethylene, and combinations thereof.

15. The balloon of claim 1 wherein the polymeric layer comprises at least about 40 weight percent polyesteretheramide copolymer.

16. The balloon of claim 15 wherein the polymeric
layer comprises at least about 80 weight percent
polyesteretheramide copolymer.

17. A balloon for an angioplasty device having a single polymeric layer consisting essentially of a polyesteretheramide copolymer.

18. The balloon of claim 17 wherein the polyesteretheramide copolymer comprises a block copolymer.

19. The balloon of claim 17 wherein the 5 polyesteretheramide copolymer has a hardness of from about 45 Shore D to about 78 Shore D.

20. The balloon of claim 19 wherein the 10 polyesteretheramide copolymer has a hardness of from about 55 Shore D to about 75 Shore D.

21. The balloon of claim 20 wherein the polyesteretheramide copolymer has a hardness of from about 63 to about 72 Shore D.

22. The balloon of claim 21 wherein the 15 polyesteretheramide copolymer has a hardness selected from about 63 Shore D, about 70 Shore D, and about 72 Shore D.

23. The balloon of claim 17 consisting of a 20 polyesteretheramide copolymer.

24. A balloon for an angioplasty device having a single polymeric layer comprising (a) at least 91 weight percent polyesteretheramide copolymer, (b) from 0 to 9 weight percent polyamide, and (c) from 0 to 9 weight percent of 25 a polymer other than polyesteretheramide and polyamide.

25. The balloon of claim 24 comprising at least about 95 weight percent polyesteretheramide copolymer.

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FIG. 1

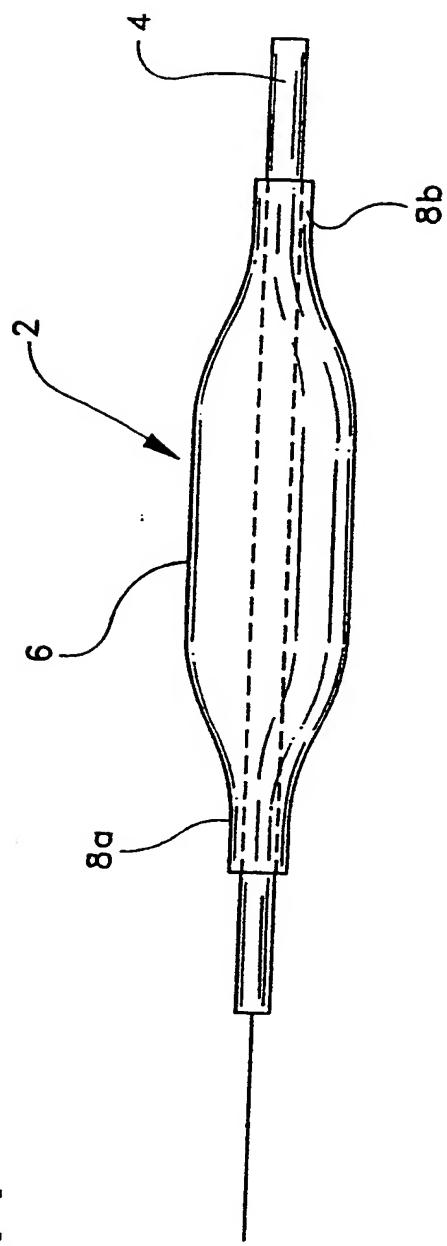
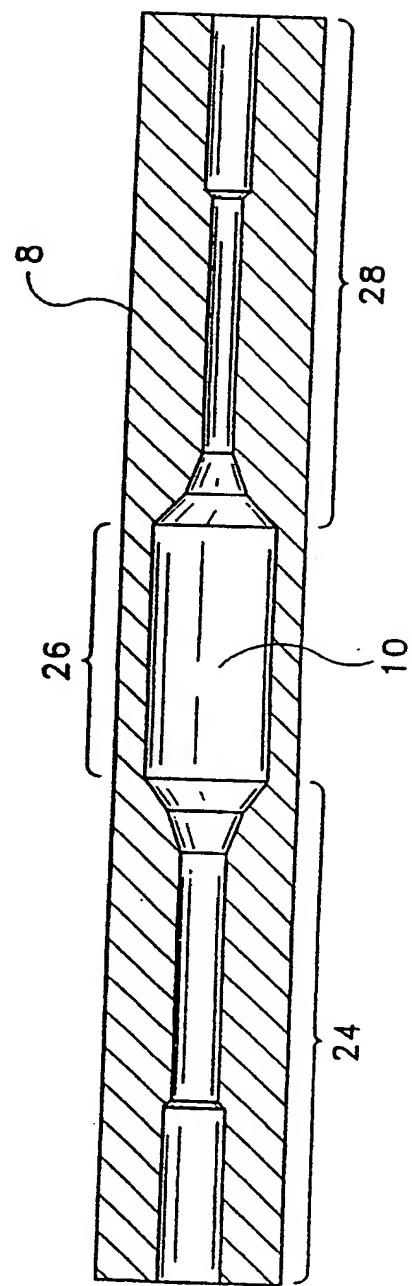


FIG. 2



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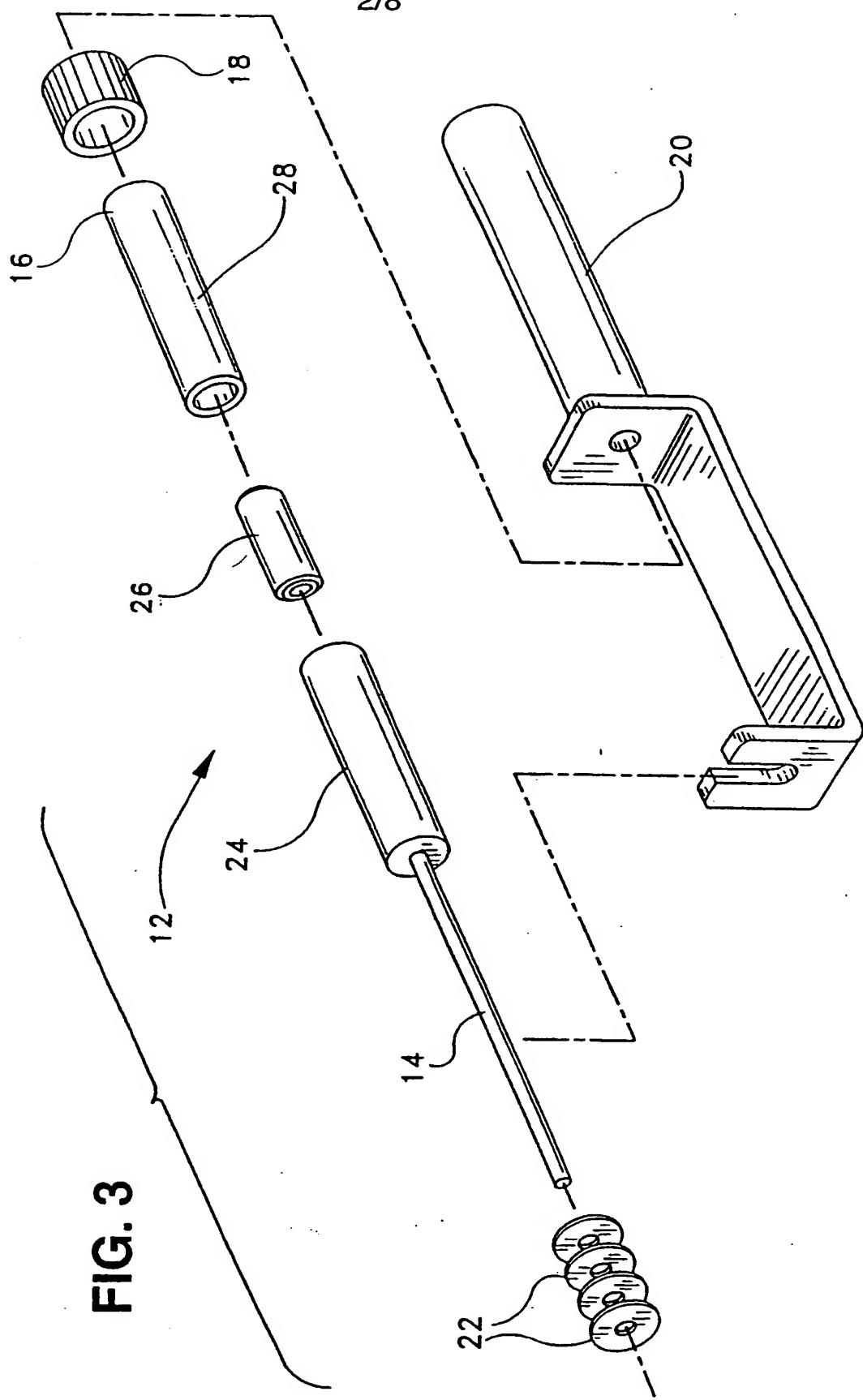


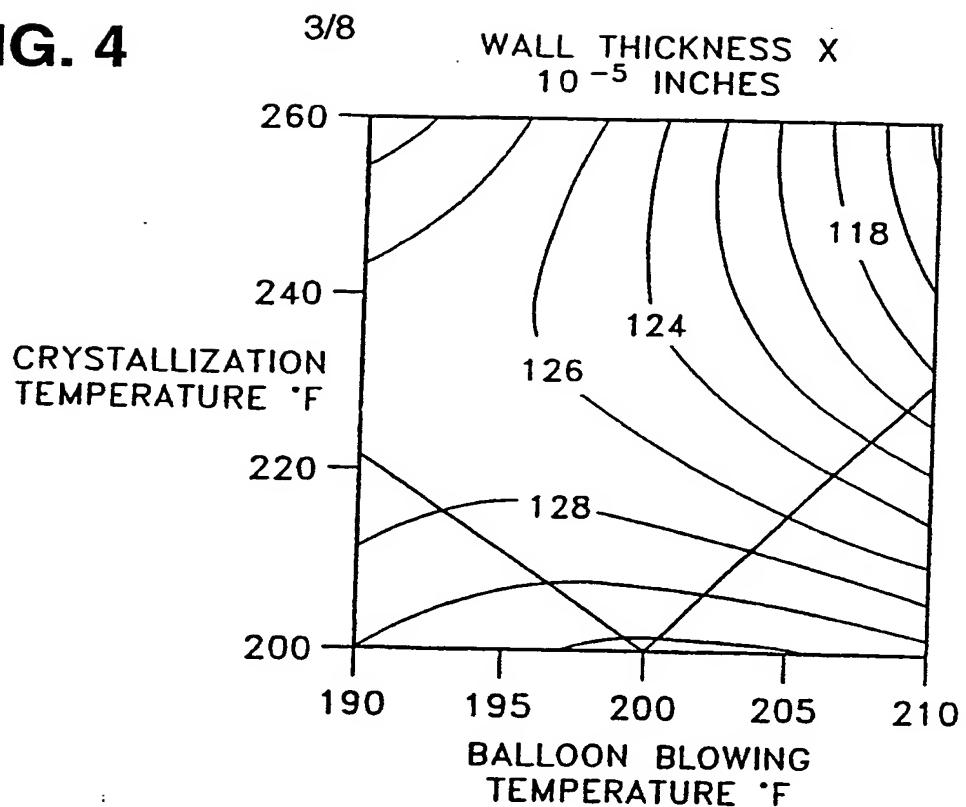
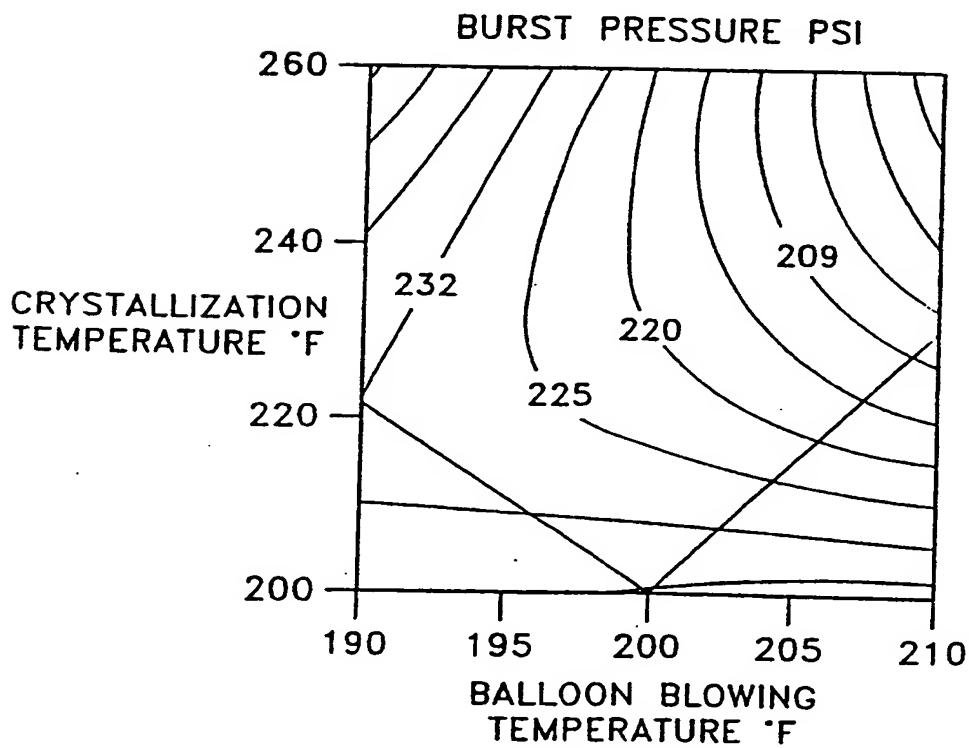
FIG. 4**FIG. 5**

FIG. 6

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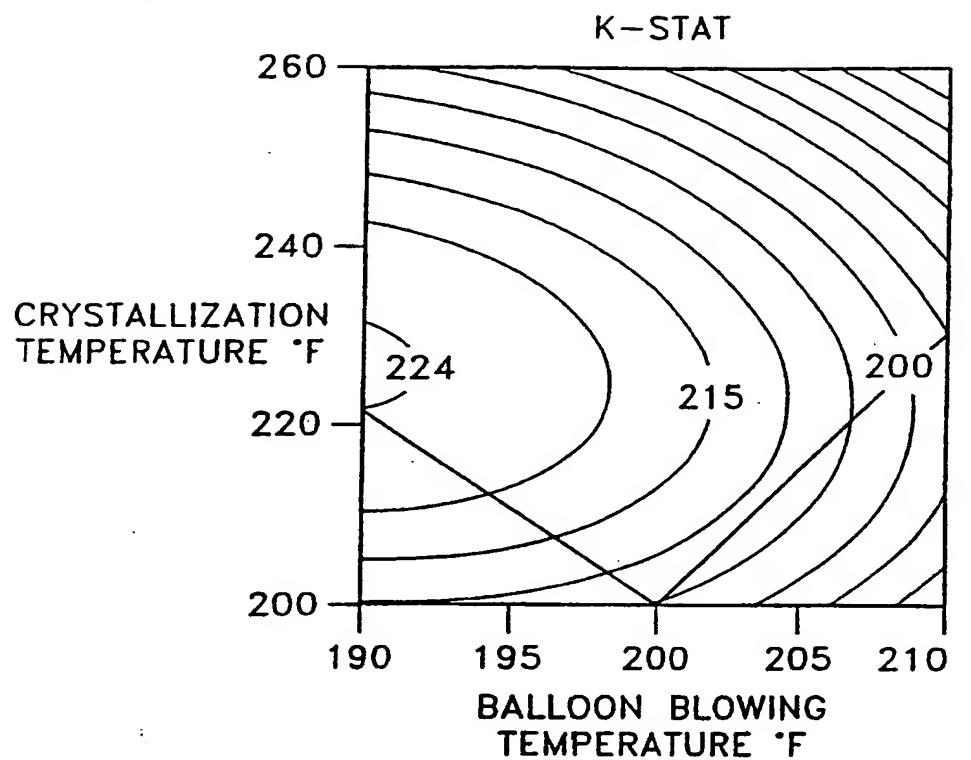
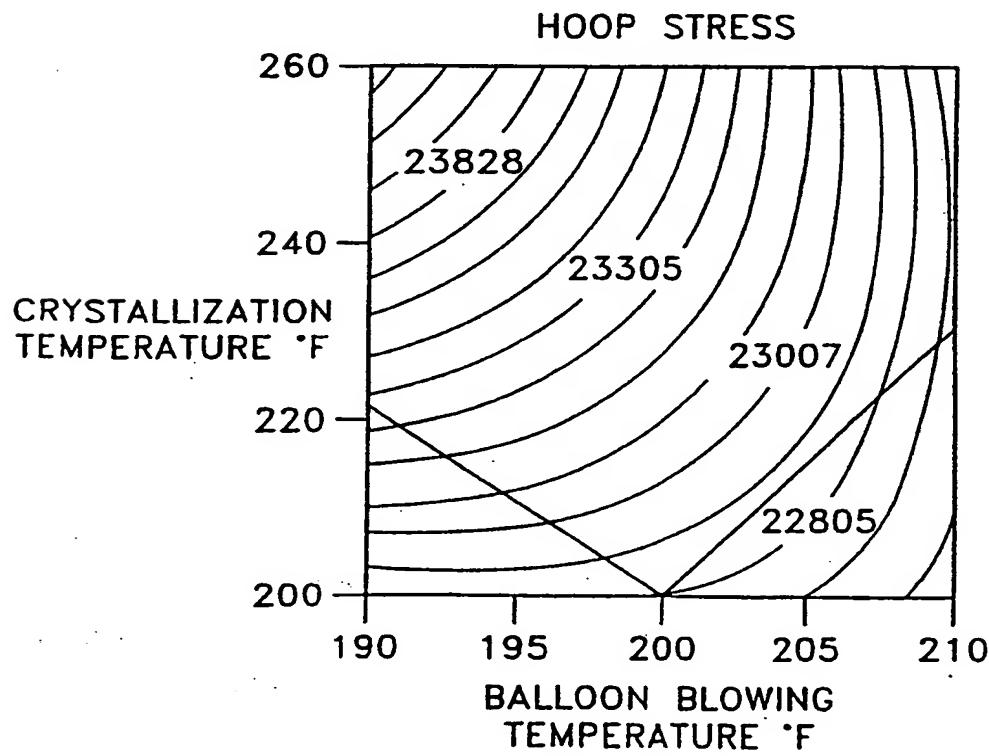
**FIG. 7**

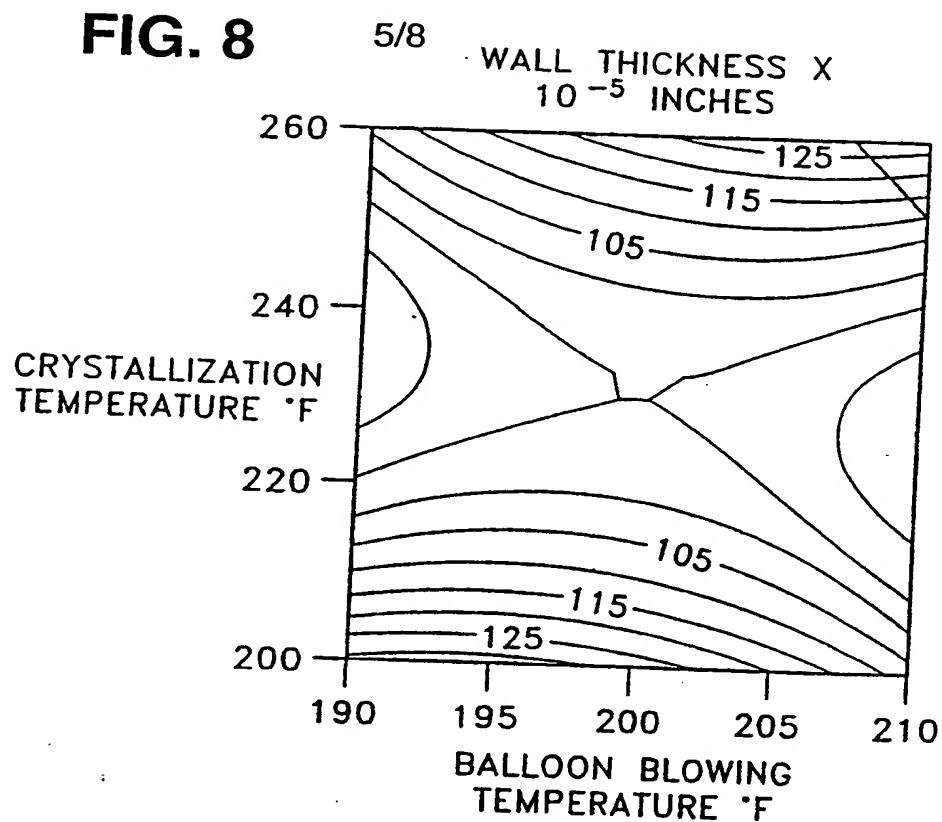
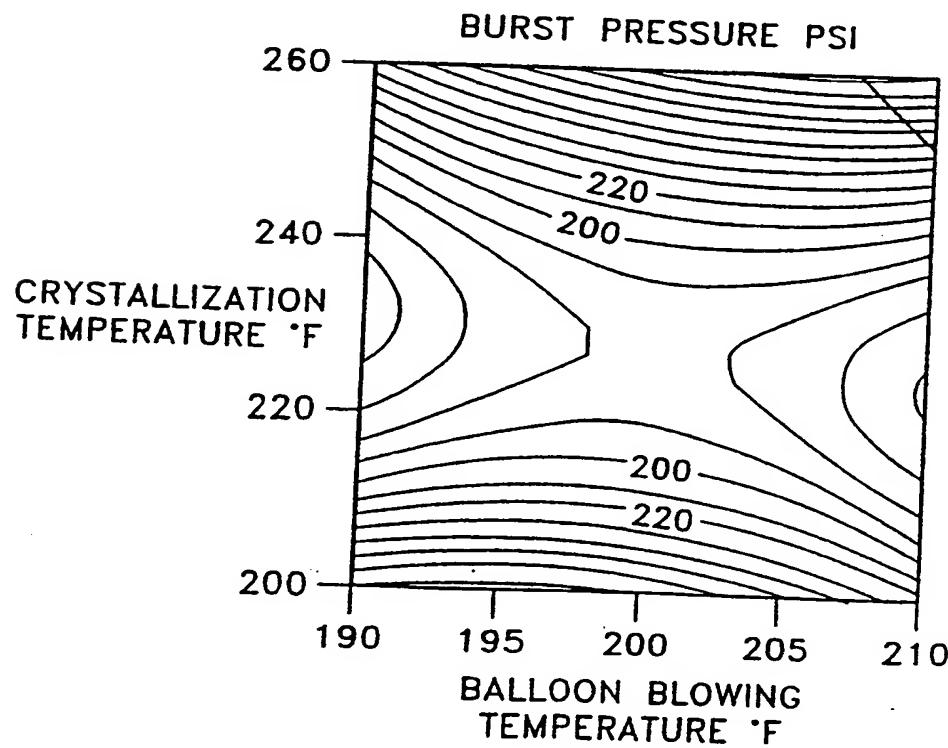
FIG. 8**FIG. 9**

FIG. 10

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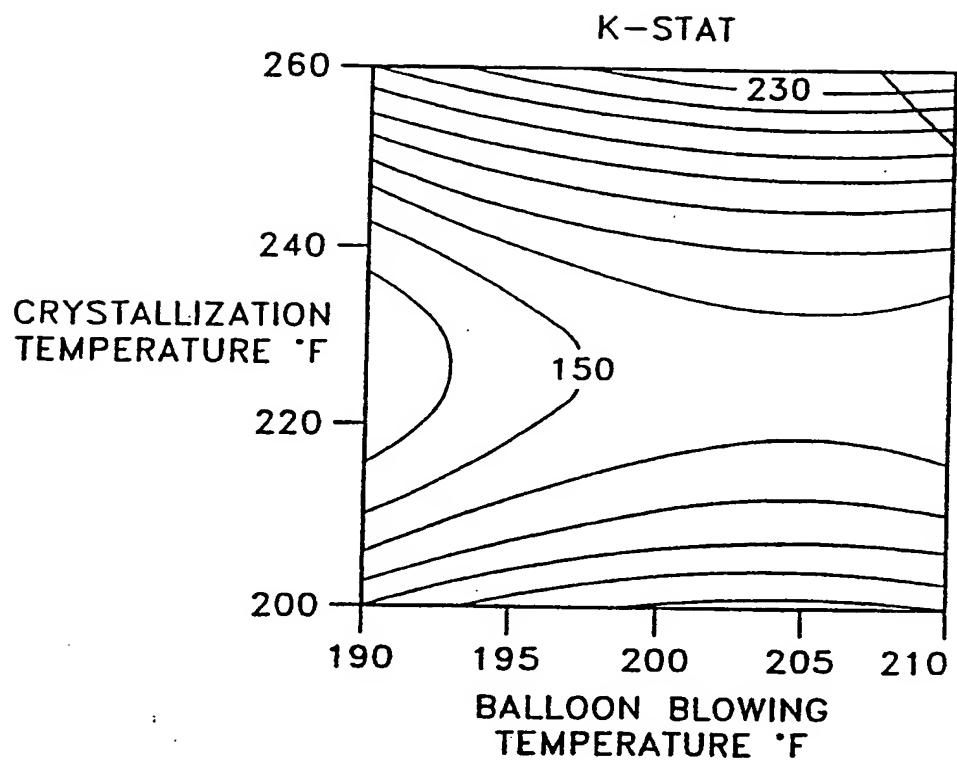
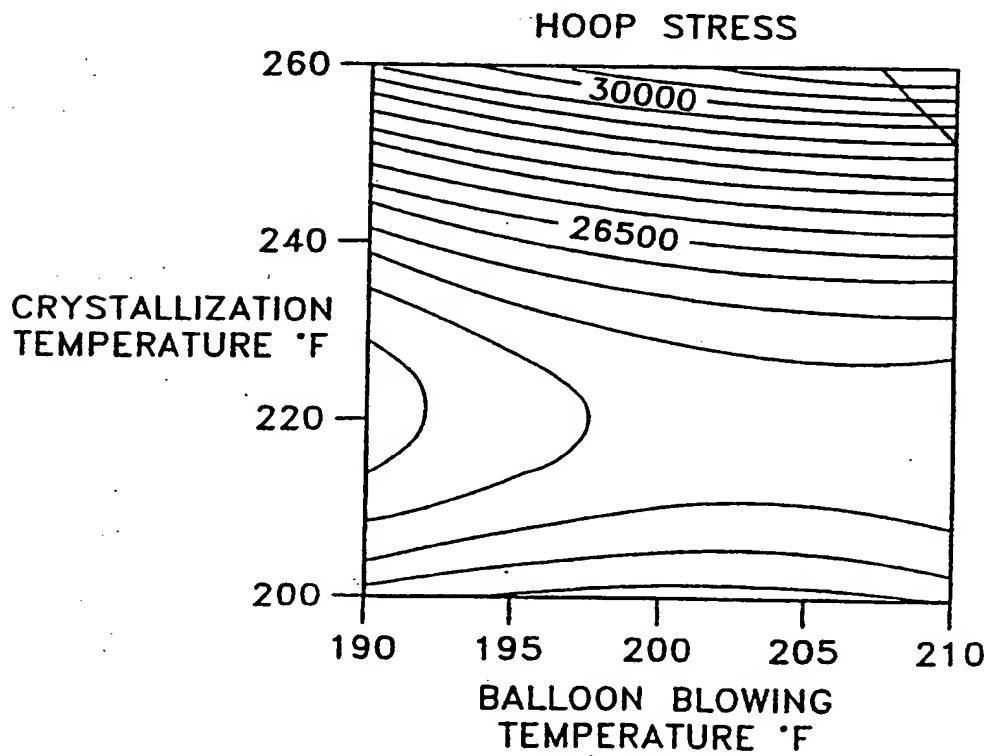
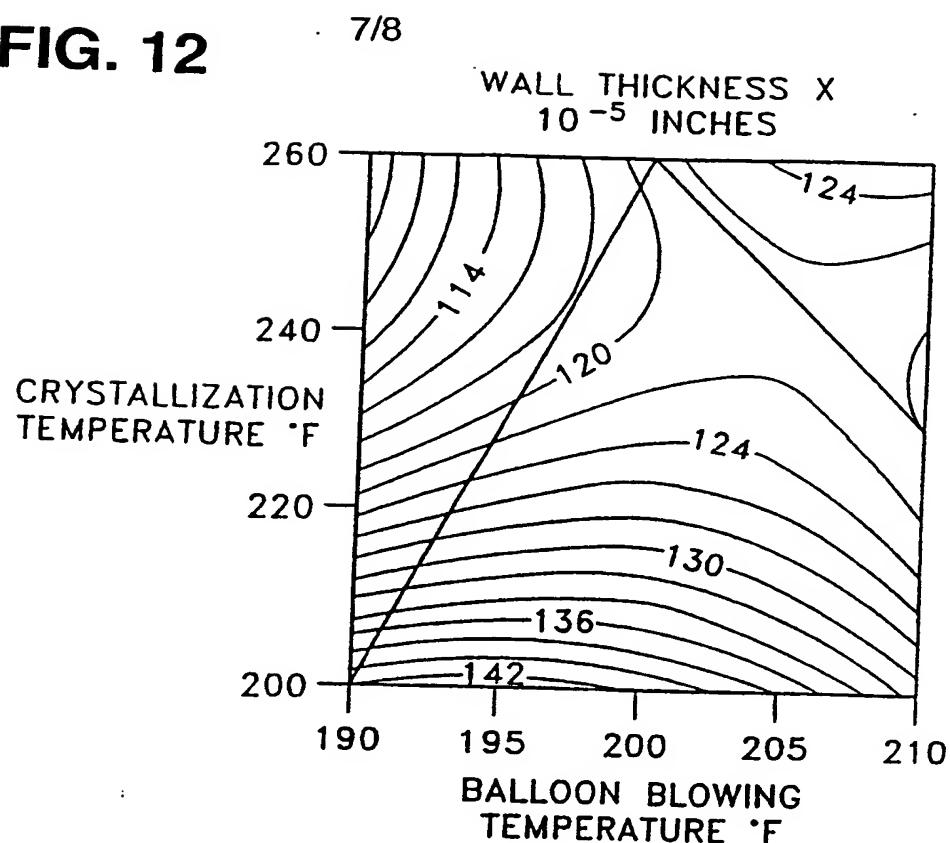
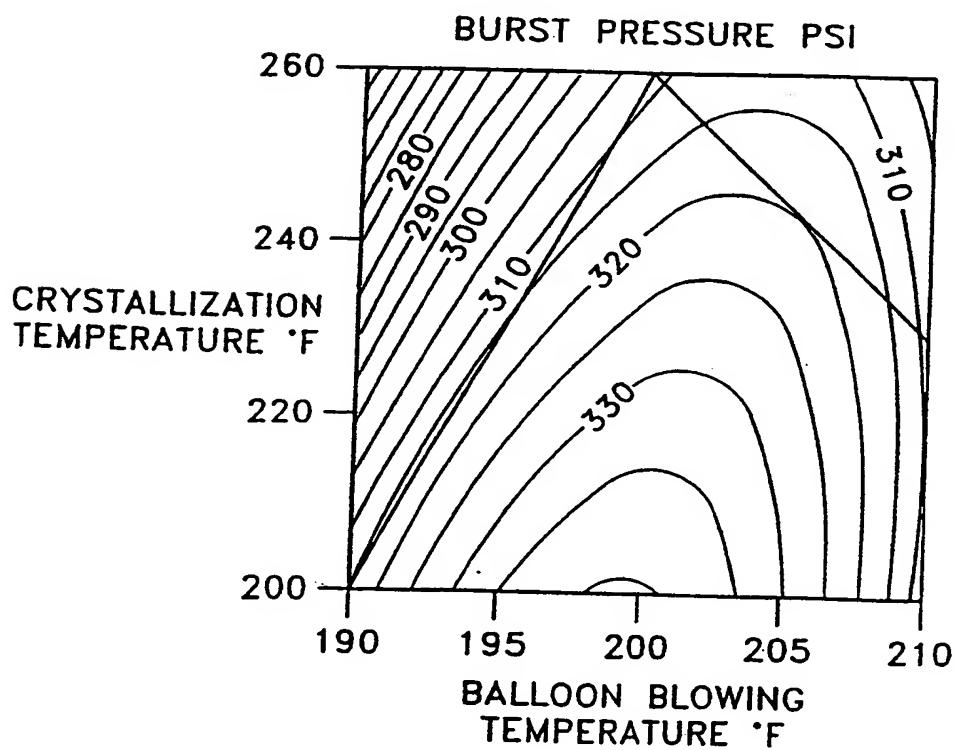
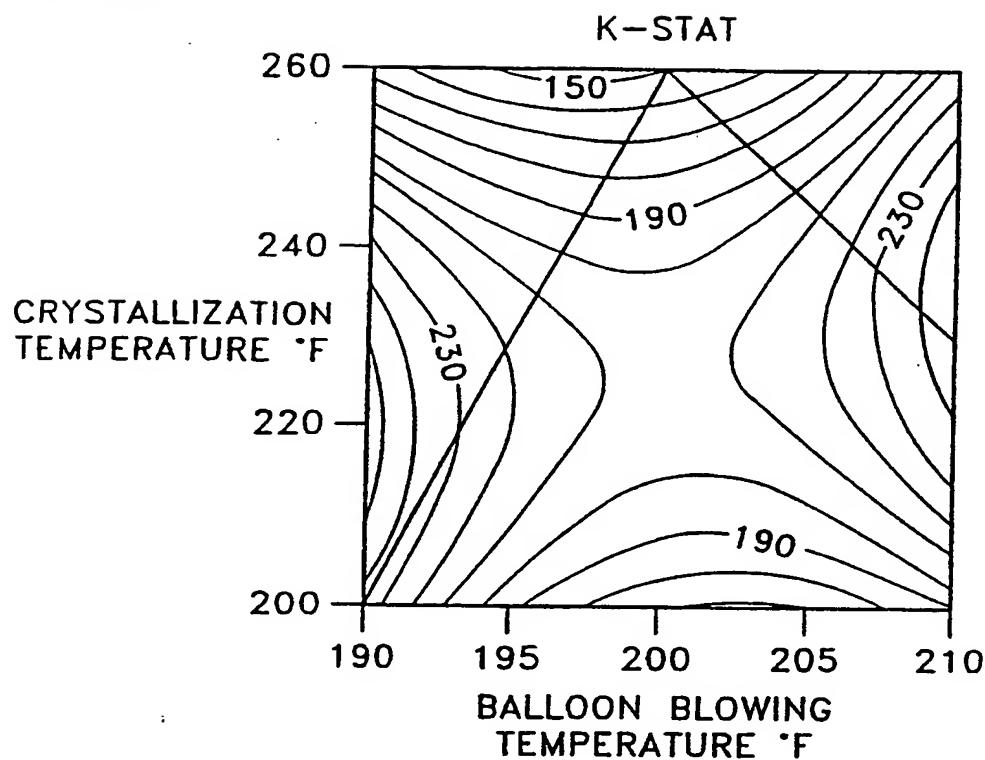
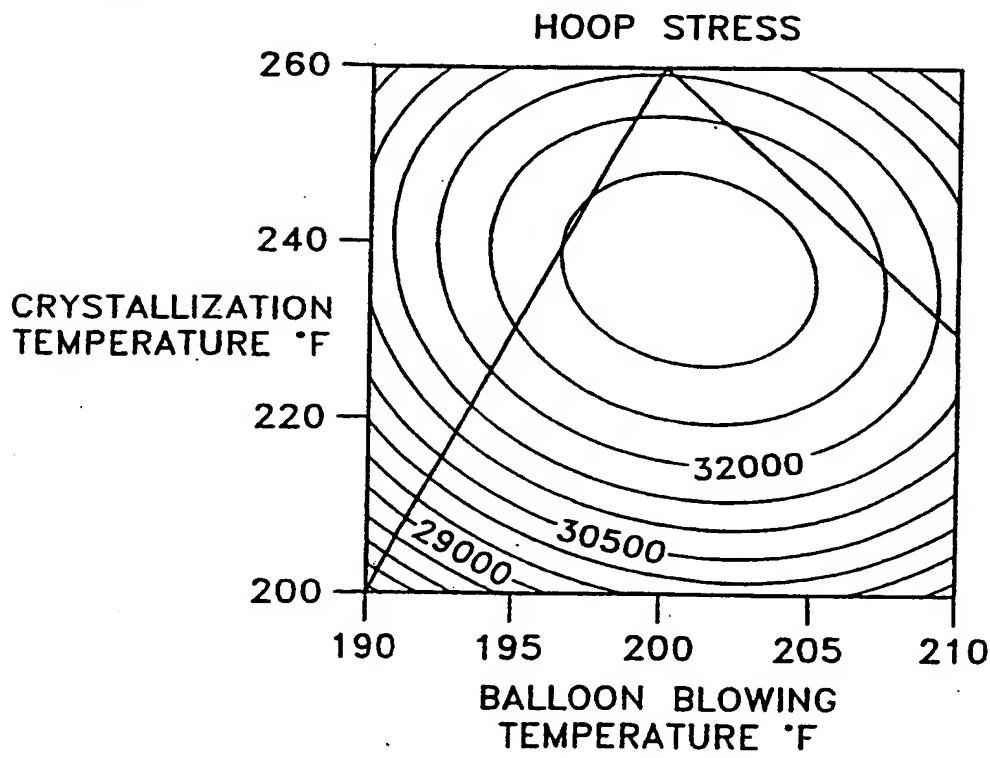
**FIG. 11**

FIG. 12**FIG. 13**

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FIG. 14**FIG. 15**

INTL NATIONAL SEARCH REPORT

International Application No
PCT/IB 96/00291

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61L29/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO,A,95 23619 (SCIMED LIFE SYSTEMS) 8 September 1995 see page 5, line 2 - page 6, line 24 see claims 1-4; examples 1-9,11,13 ---	1,2,4-7, 15-25
P,X	EP,A,0 697 219 (ADVANCED CARDIOVASCULAR SYSTEMS) 21 February 1996 see page 5, line 15 - line 16; claim 3 ---	1
X	EP,A,0 537 069 (TERUMO) 14 April 1993 cited in the application see claims 1,6,7 ---	1,8
A	FR,A,2 651 681 (MEDICORP RESEARCH) 15 March 1991 see claims 1,3 --- -/-	1

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

10 October 1996

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